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(12) **United States Patent**
Steelman et al.

(10) **Patent No.: US 9,364,622 B2**
(45) **Date of Patent: Jun. 14, 2016**

(54) **INHALATION DEVICES AND SYSTEMS AND METHODS INCLUDING THE SAME**

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(72) Inventors: **Peter Wayne Steelman**, Charlotte, NC (US); **James Edward Flynn**, New York, NY (US); **John Zeis**, San Marcos, CA (US); **Karla Worley-Ham**, Matthews, NC (US)

(73) Assignee: **FSC Laboratories, Inc.**, Charlotte, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 432 days.

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Related U.S. Application Data

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(51) **Int. Cl.**

A61M 15/00	(2006.01)
A61M 16/10	(2006.01)
A61M 16/20	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 15/0086*** (2013.01); ***A61M 15/0013*** (2014.02); ***A61M 15/0018*** (2014.02);
(Continued)

(58) **Field of Classification Search**

CPC A61M 15/00; A61M 15/0013; A61M 15/0015; A61M 15/0016; A61M 15/0018; A61M 15/0023; A61M 15/0086; A61M 15/0088; A61M 16/20; A61M 16/209; B05B 15/068; B65D 83/30

USPC 128/200.12, 200.14, 200.22, 200.23, 128/203.12, 203.28, 203.29, 204.11

See application file for complete search history.

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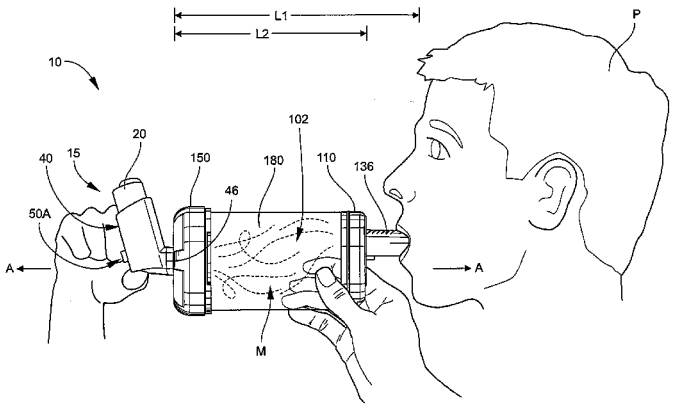
(74) *Attorney, Agent, or Firm* — Myers Bigel & Sibley, P.A.

(57) **ABSTRACT**

A collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser includes an outlet end member, an inlet end member and a tubular, pliable, collapsible sleeve member attached at either end to the inlet and outlet members. The outlet end member includes a mouthpiece. The inlet end member includes an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser. The inhalation device is positionable in each of an open position, wherein the sleeve member defines a chamber, and a closed position, wherein the sleeve member is collapsed and enveloped by the outlet end member and the inlet end member.

32 Claims, 25 Drawing Sheets



(52) **U.S. Cl.**
CPC ***A61M15/0023*** (2014.02); ***A61M 15/0088*** (2014.02); ***A61M 16/20*** (2013.01); *A61M 15/009* (2013.01); *A61M 16/208* (2013.01)

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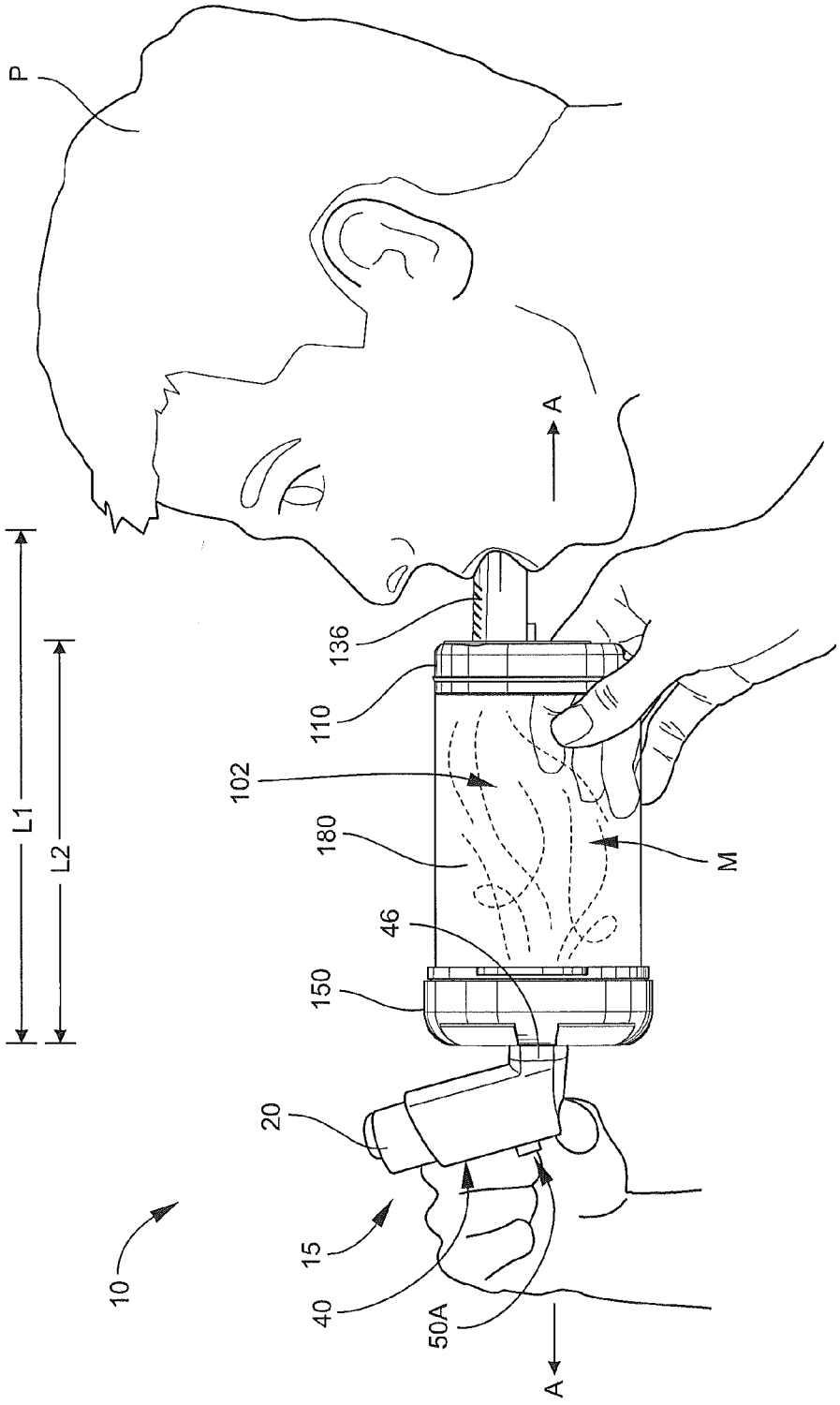

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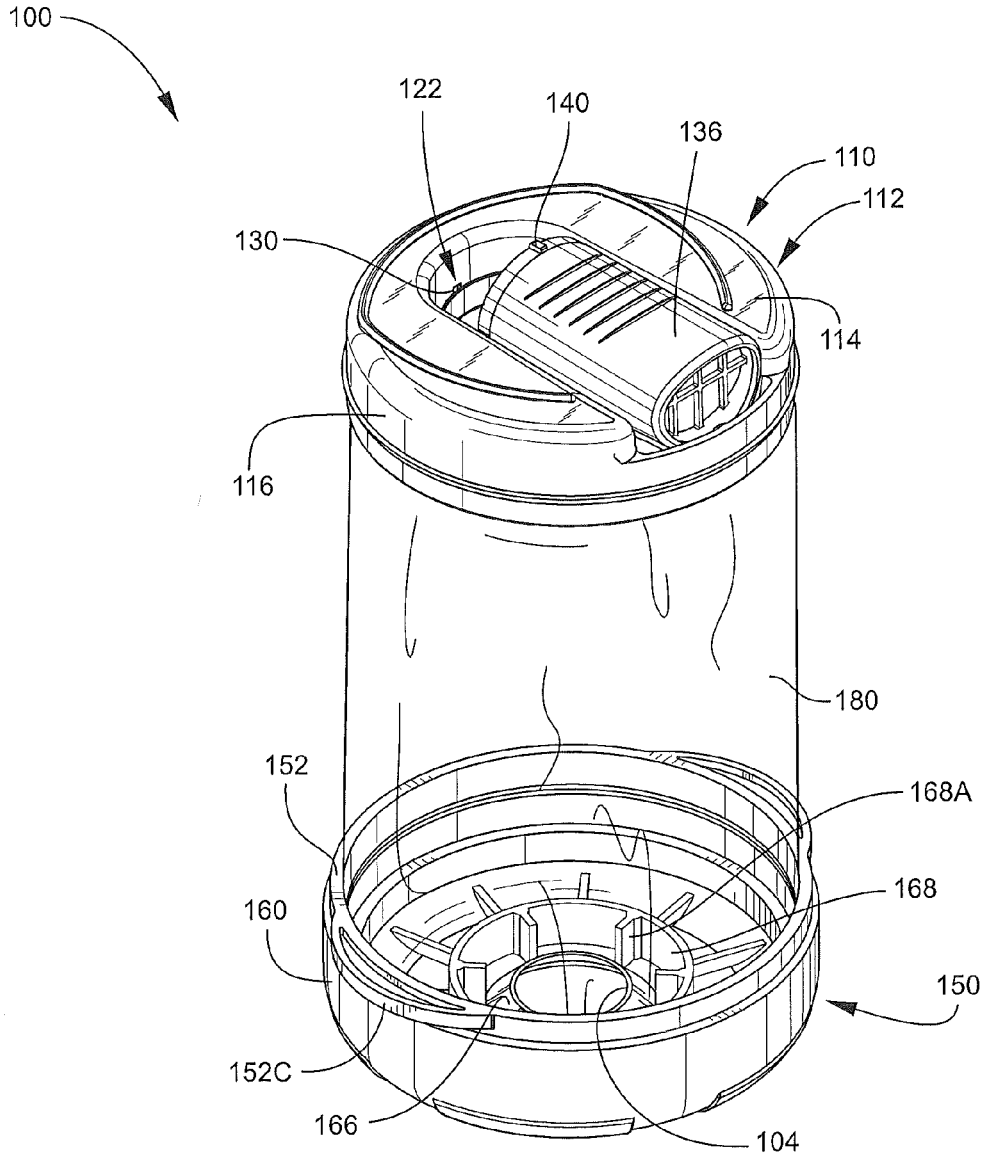
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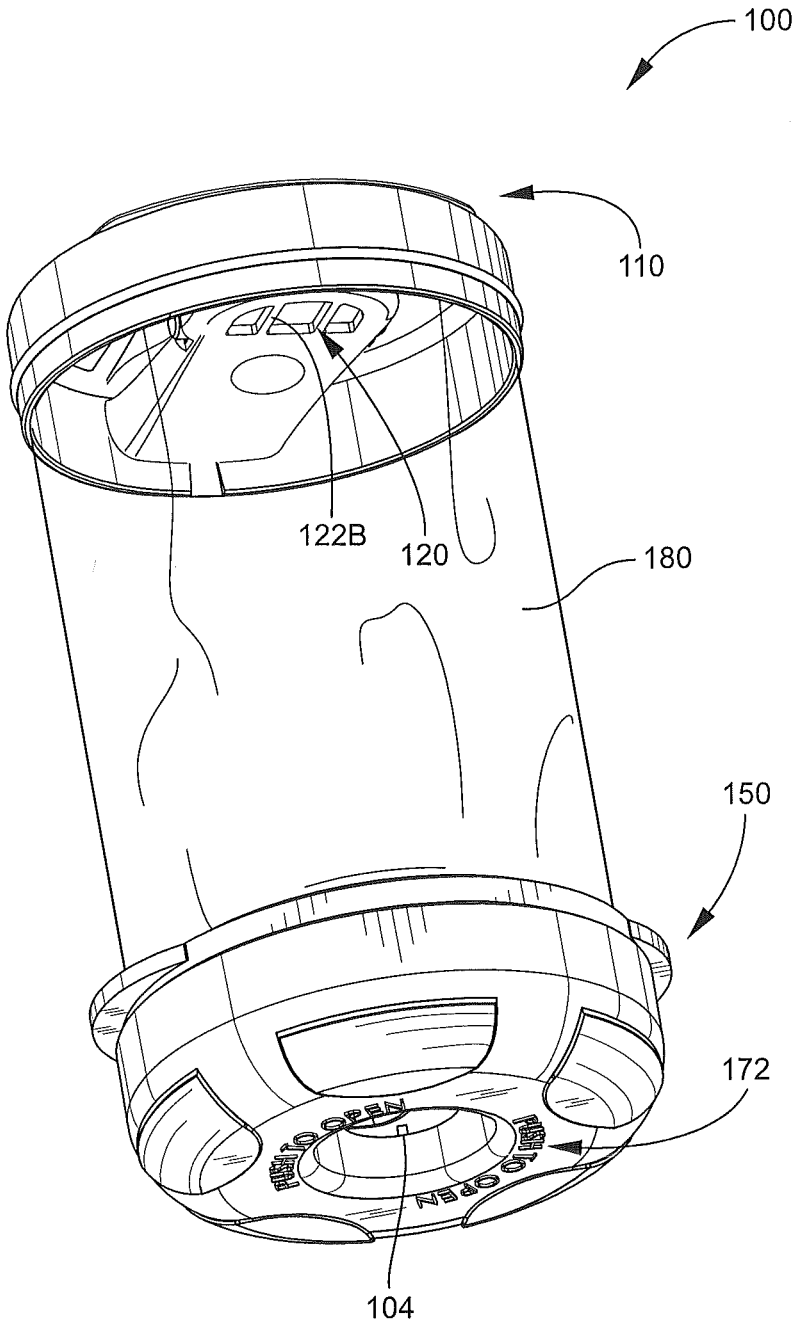

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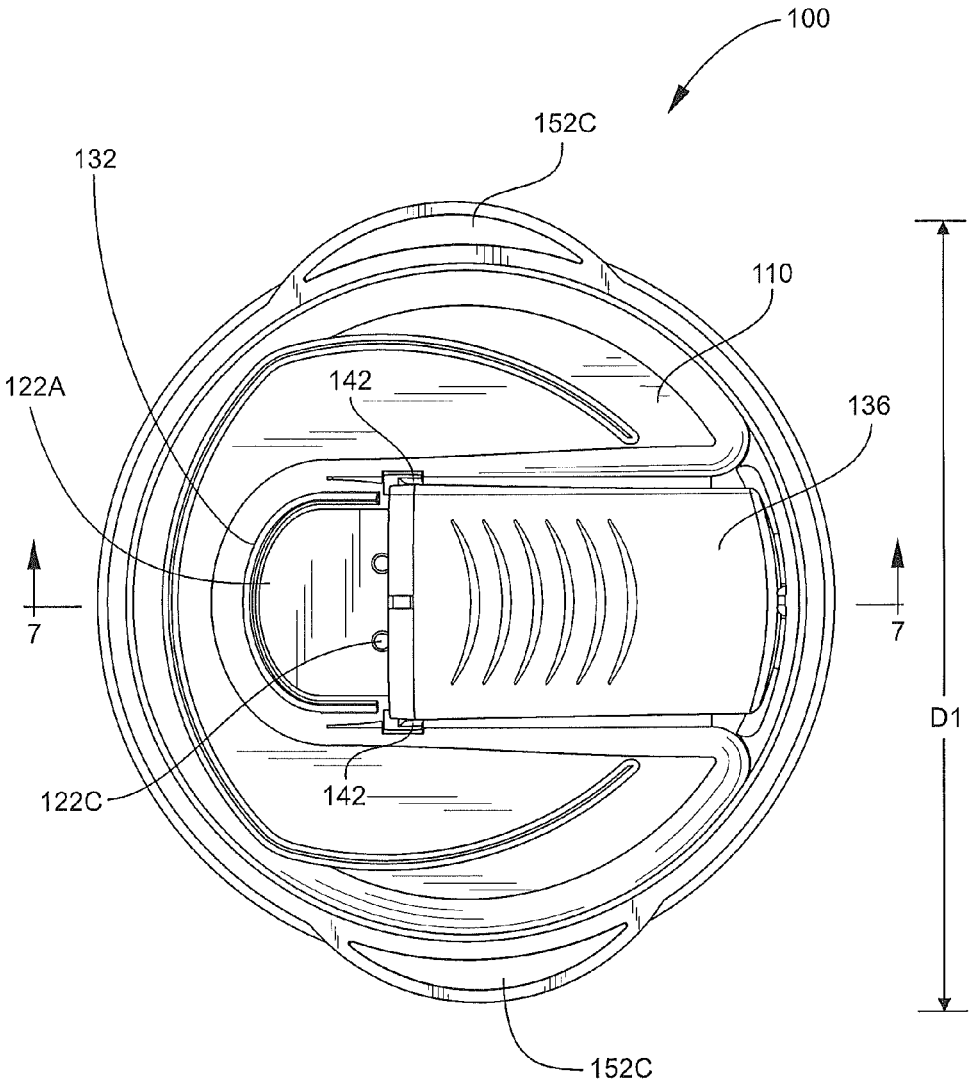

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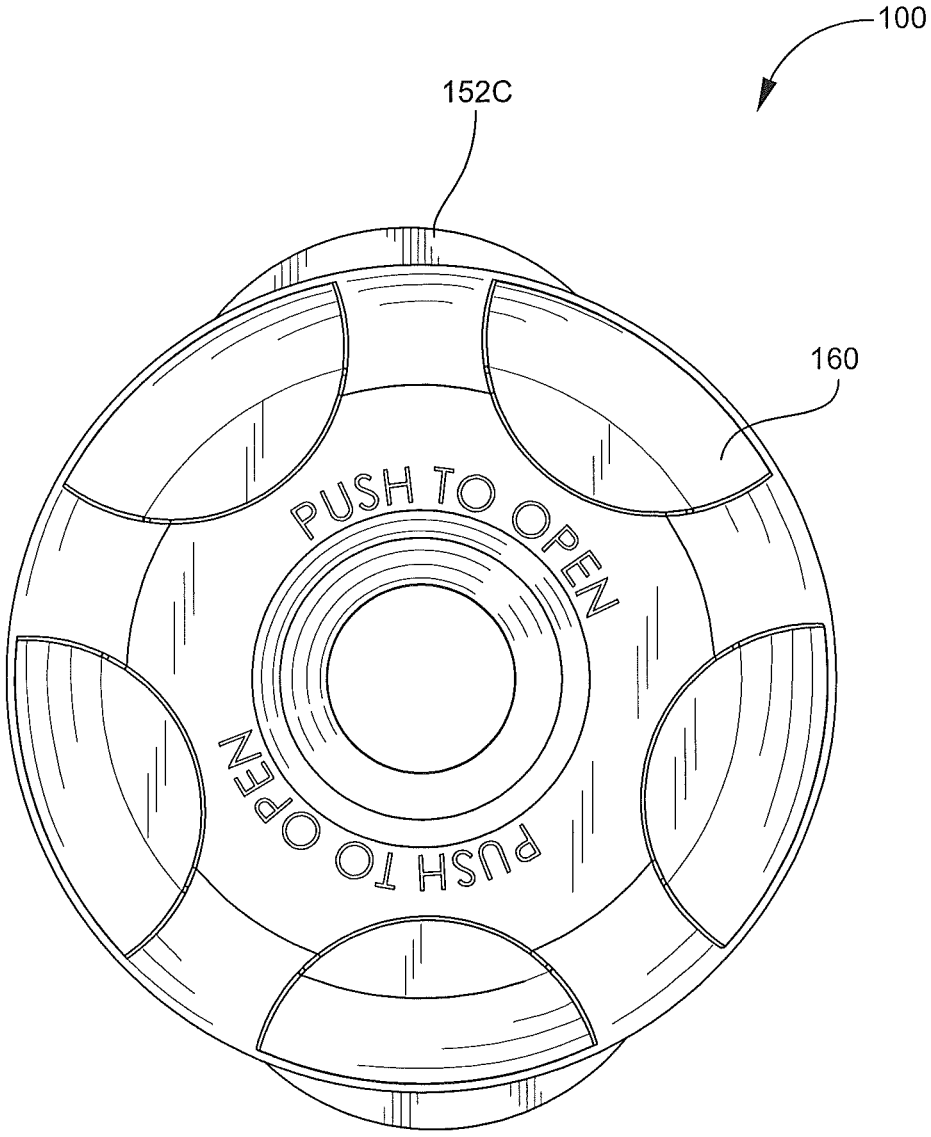

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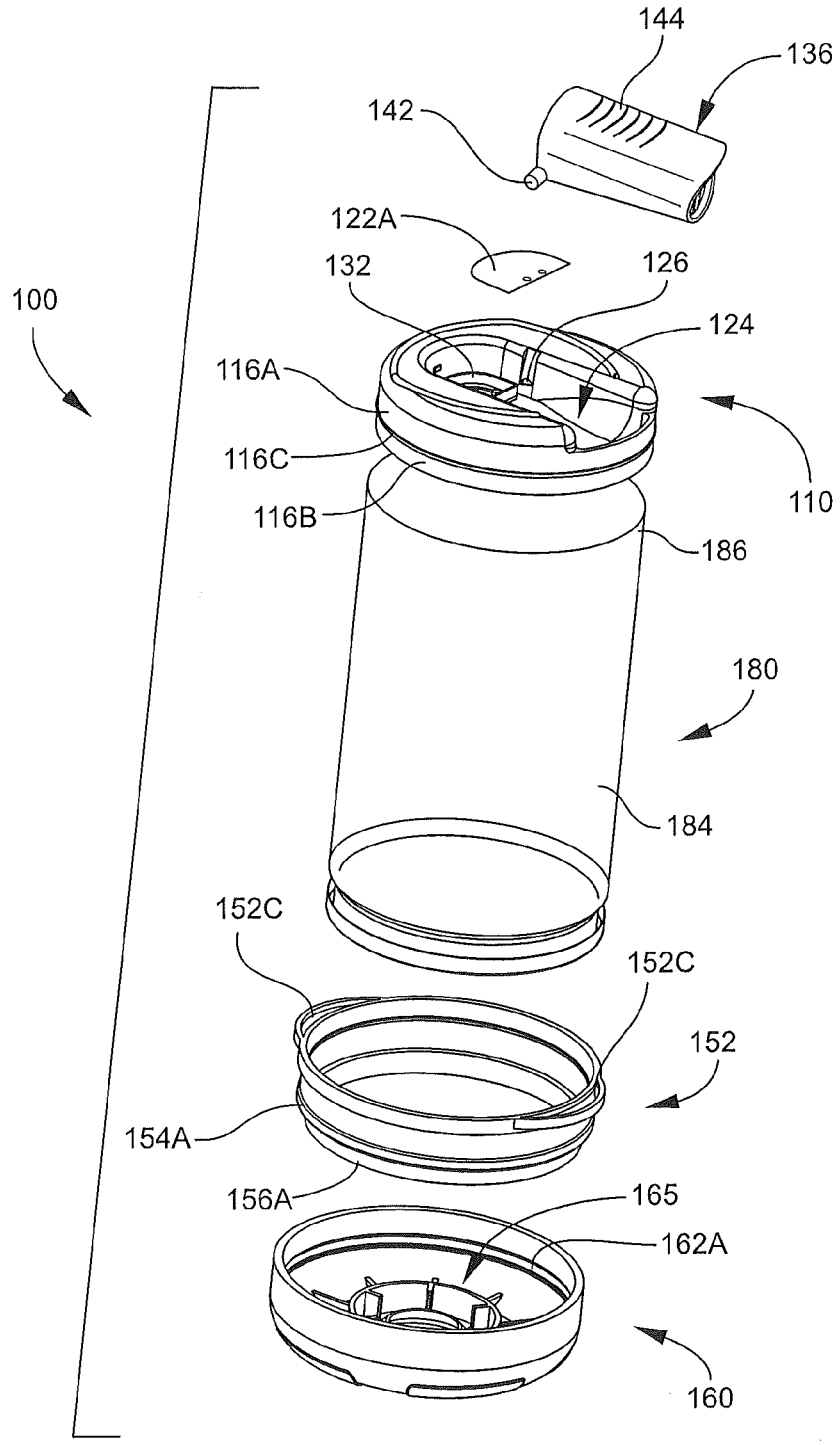
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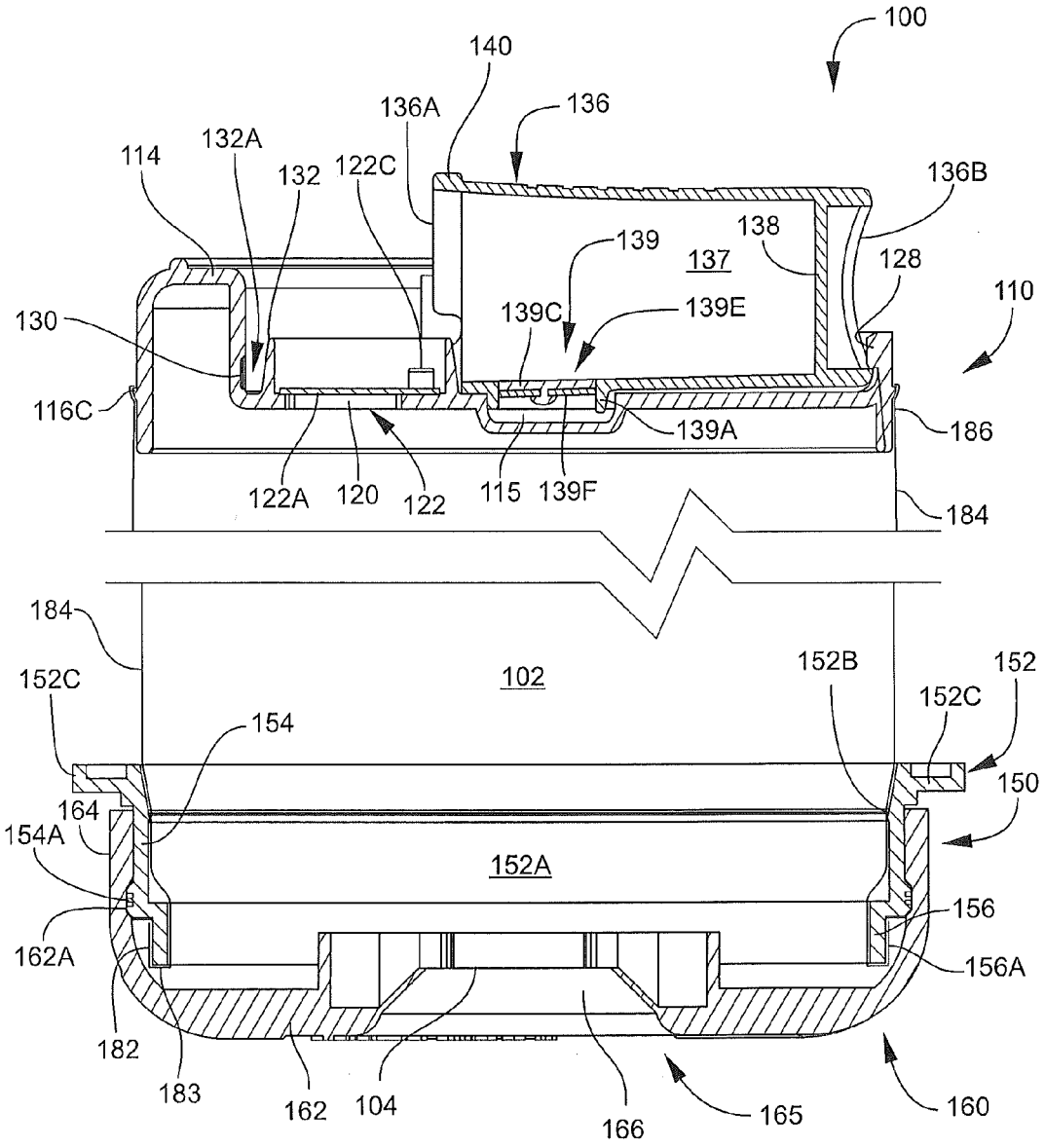
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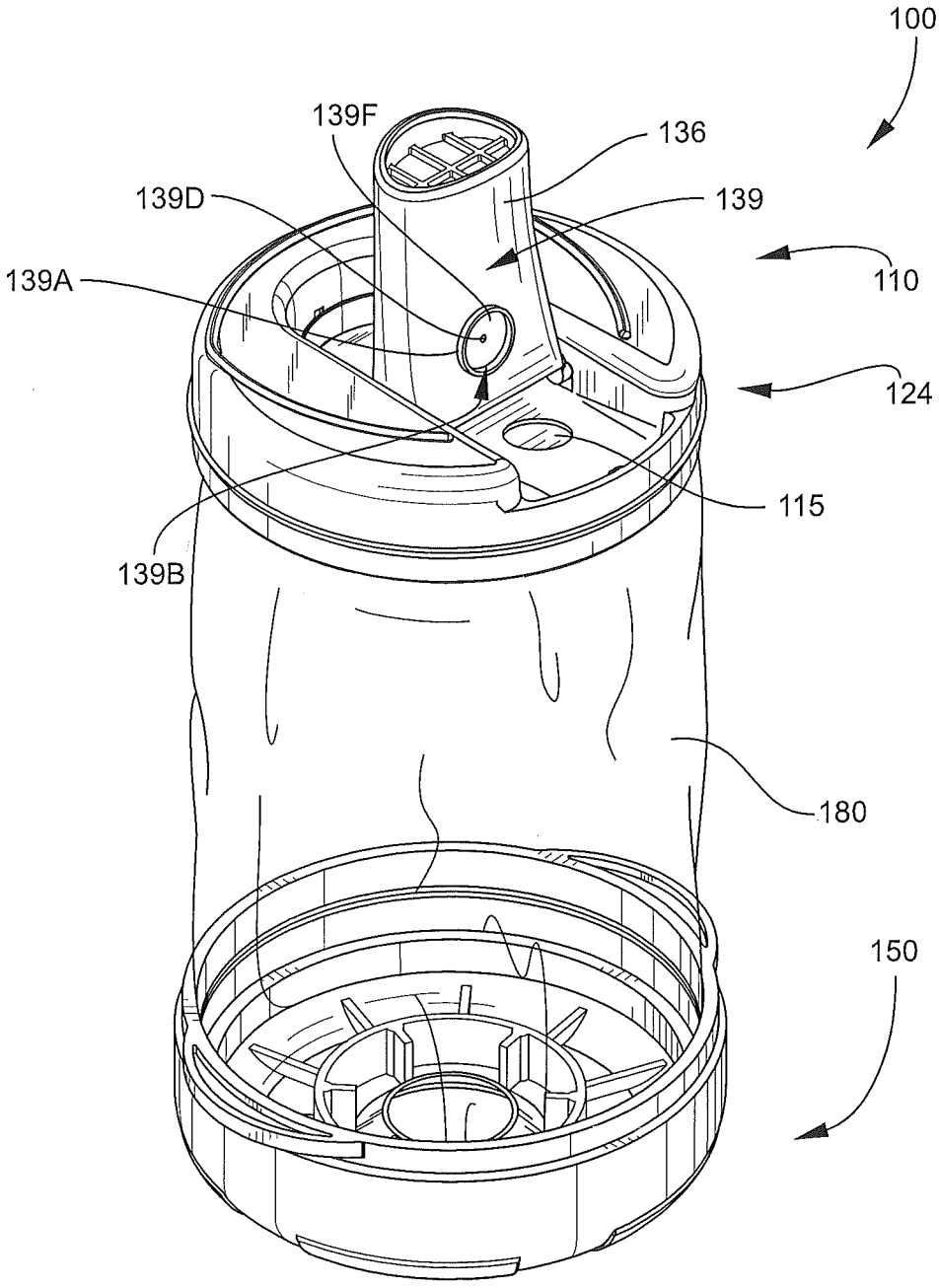
Fig. 7



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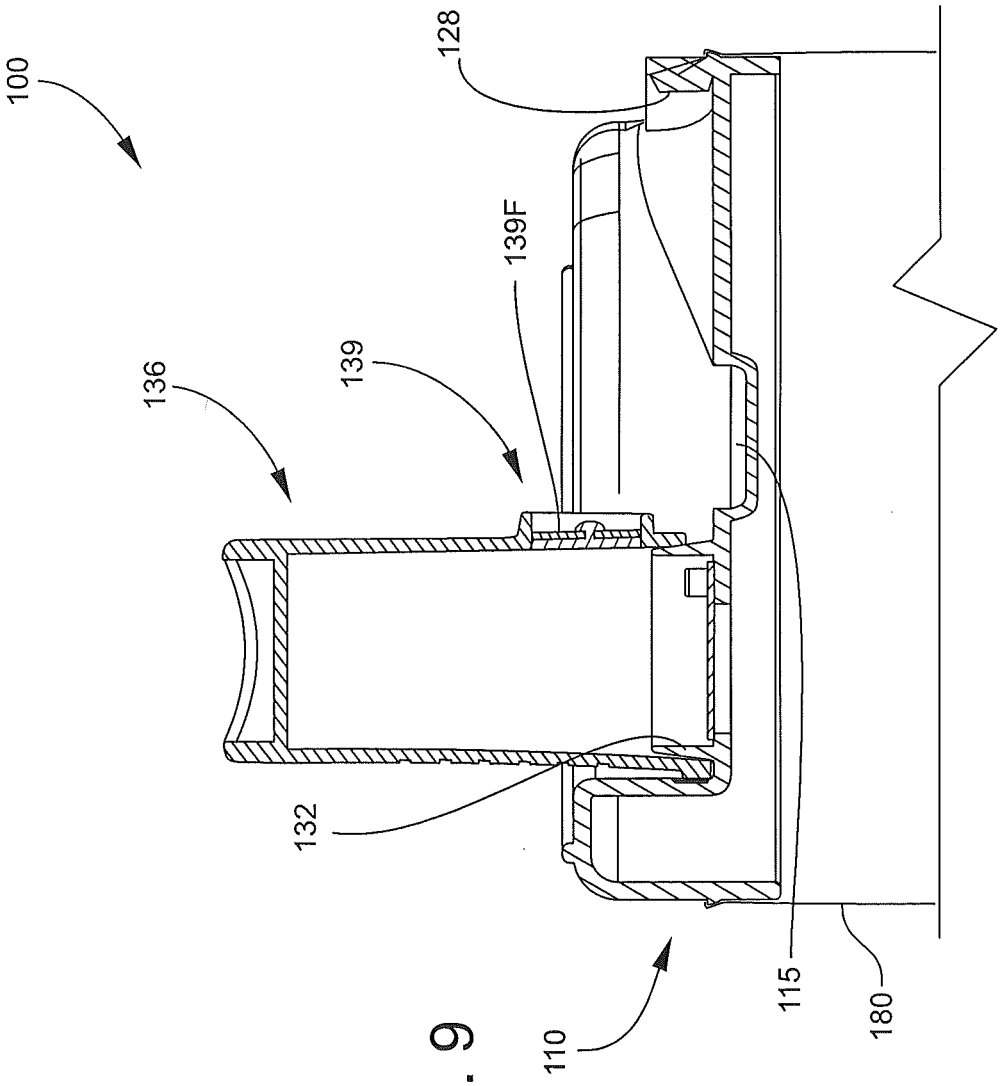

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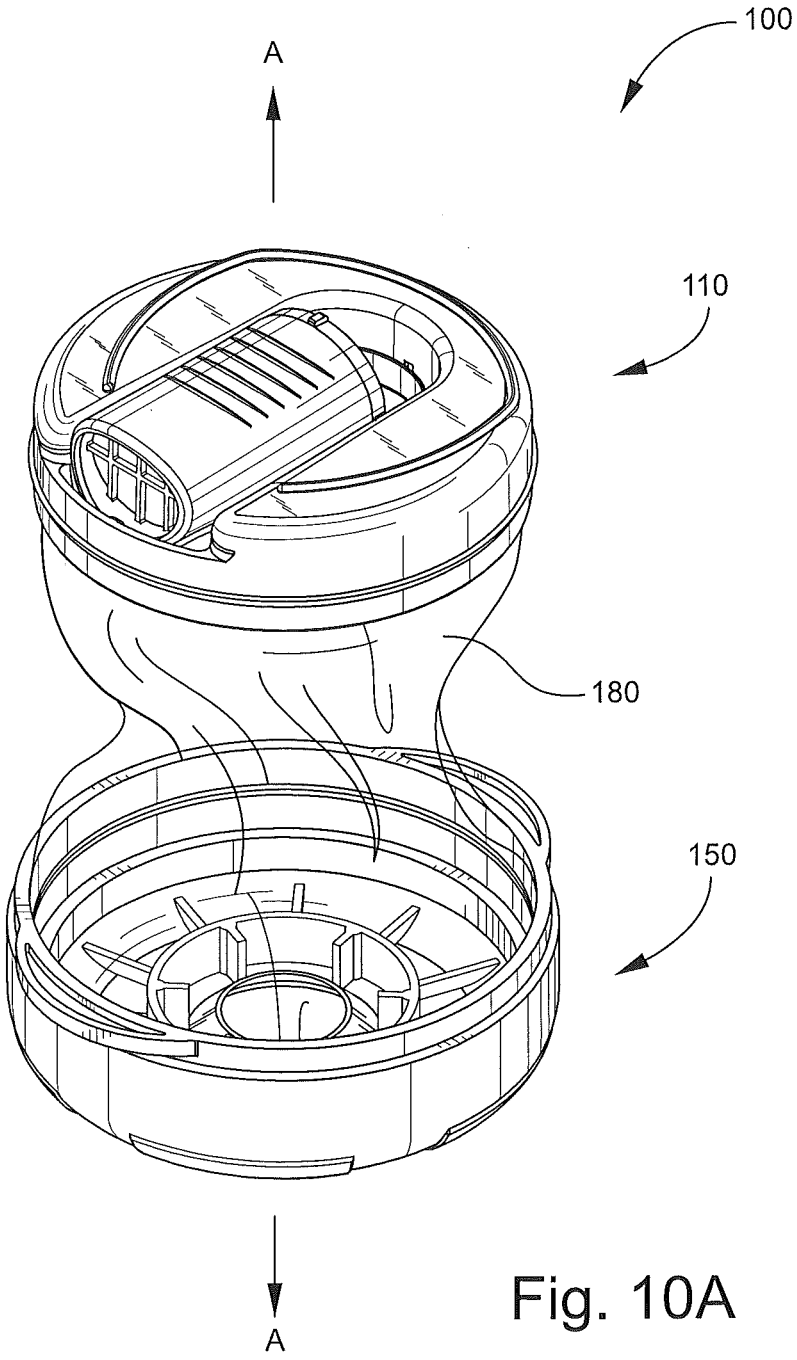

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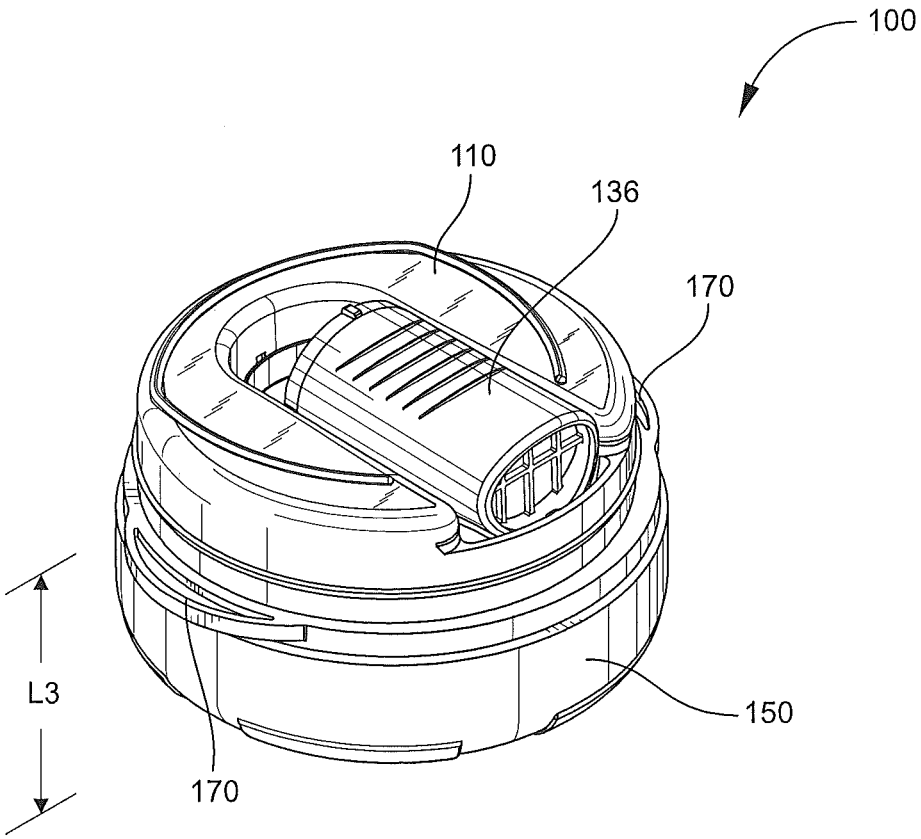

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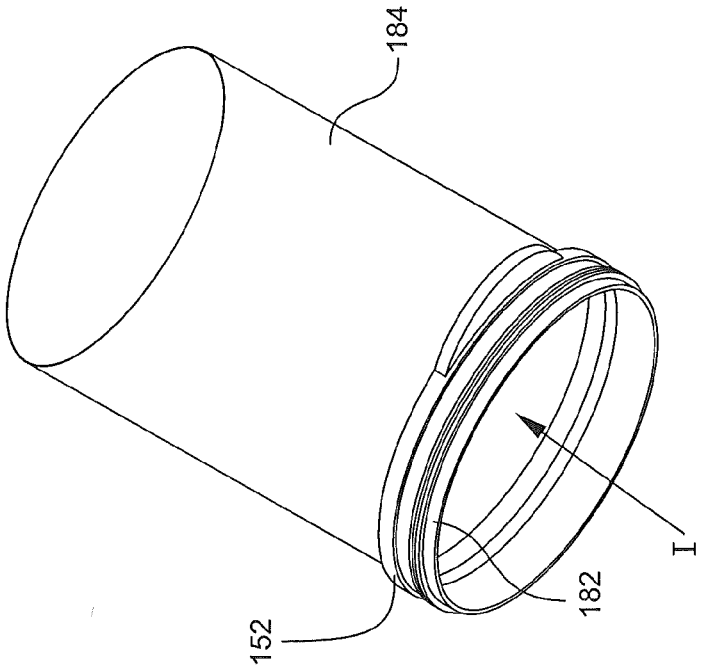

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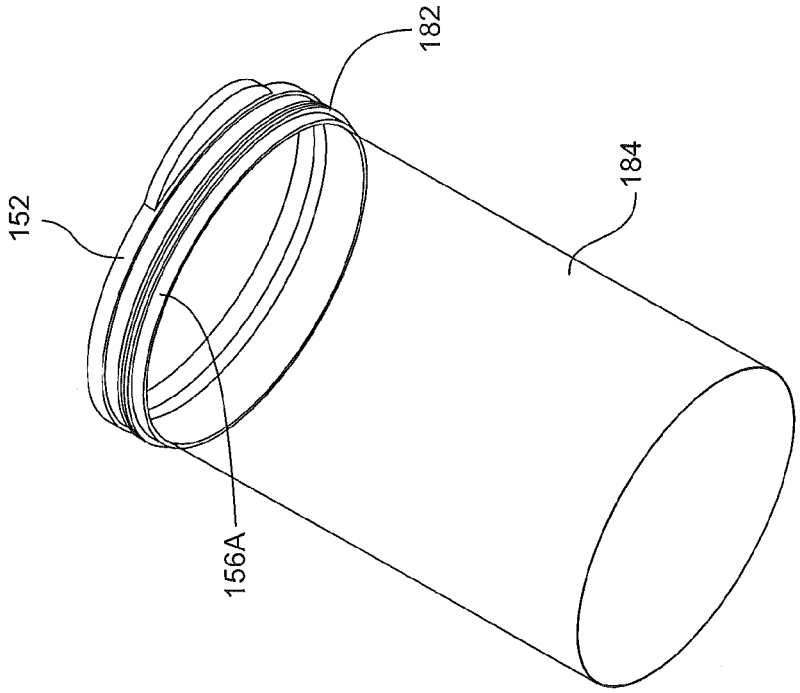

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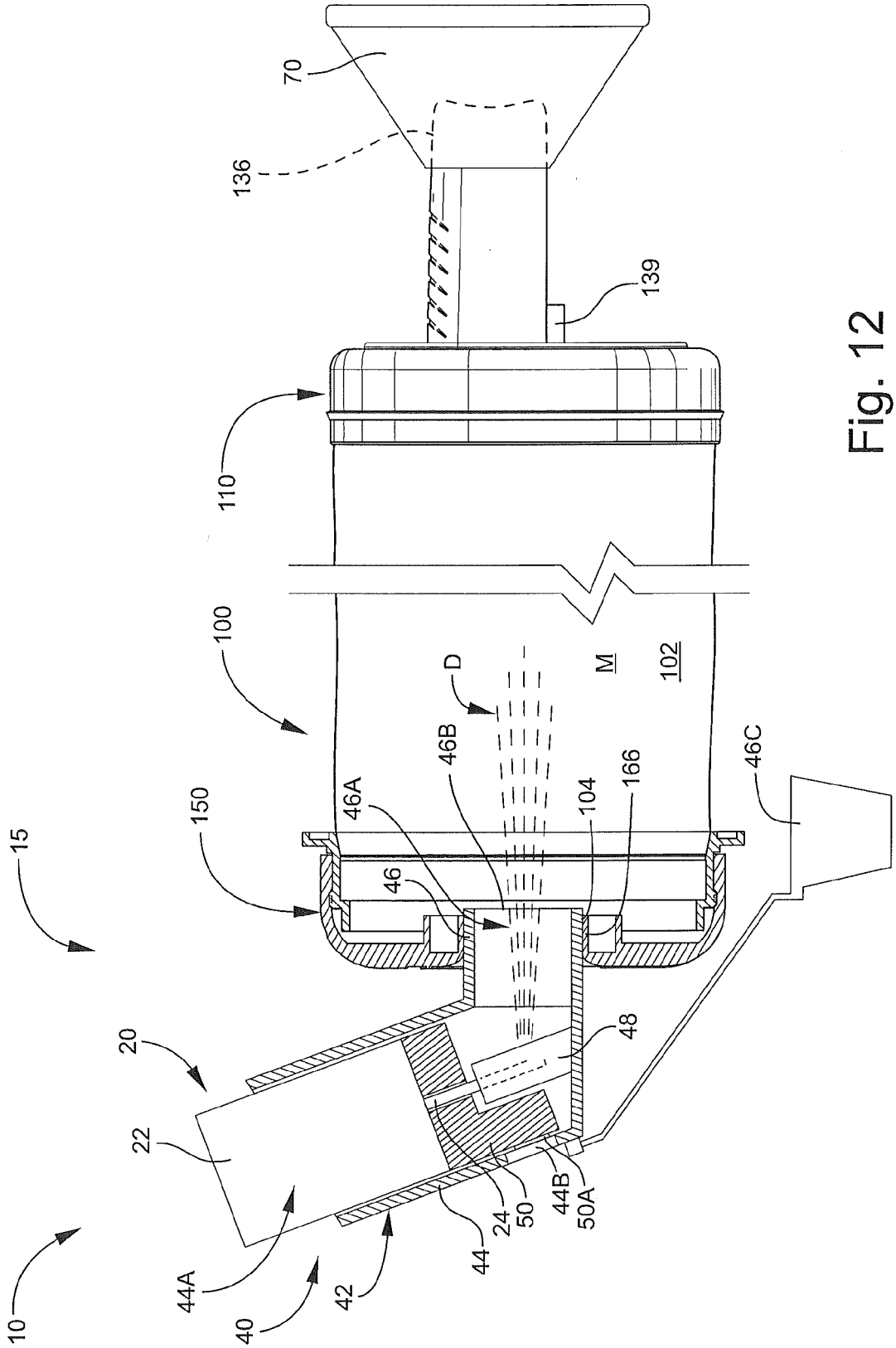
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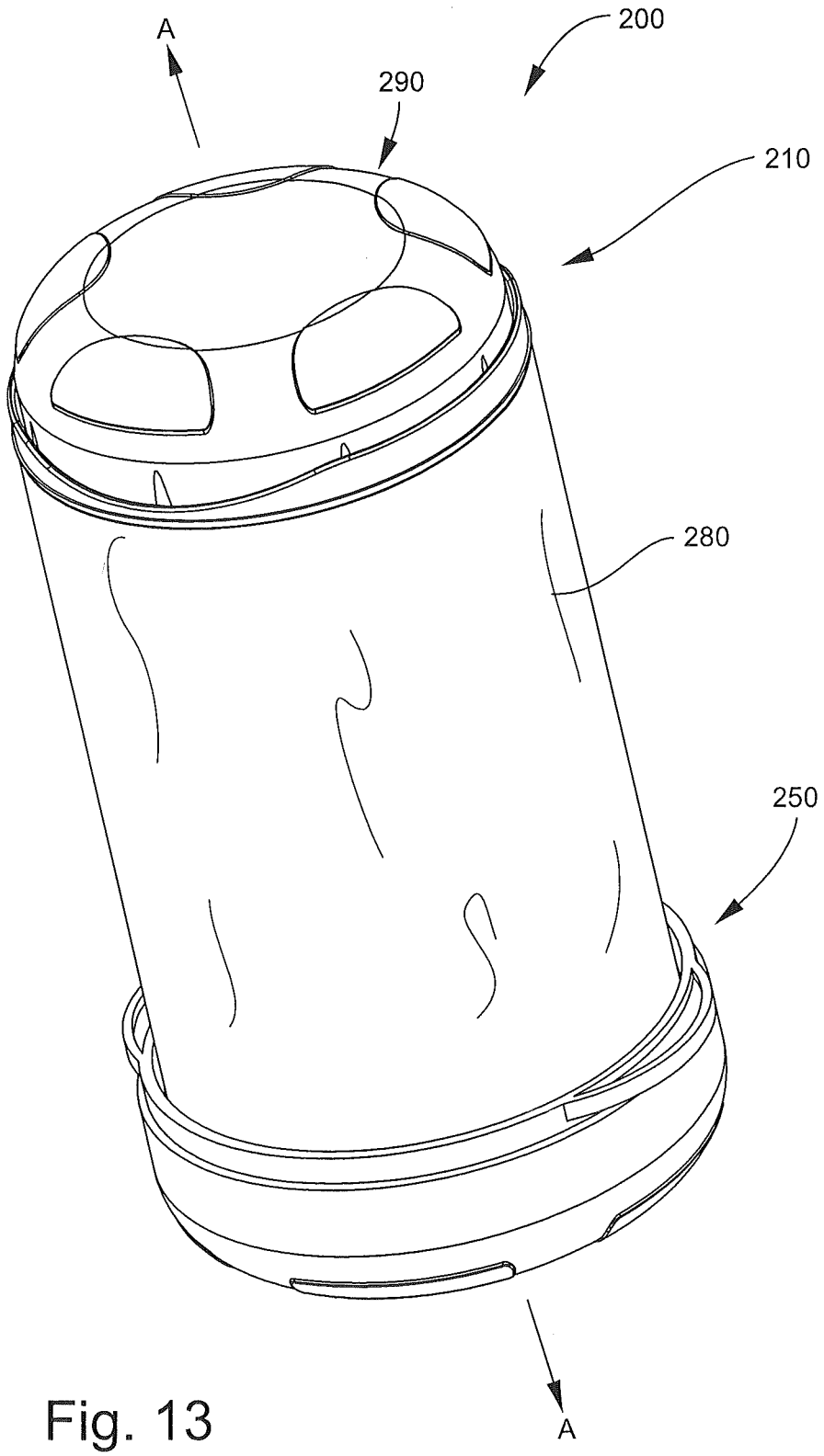

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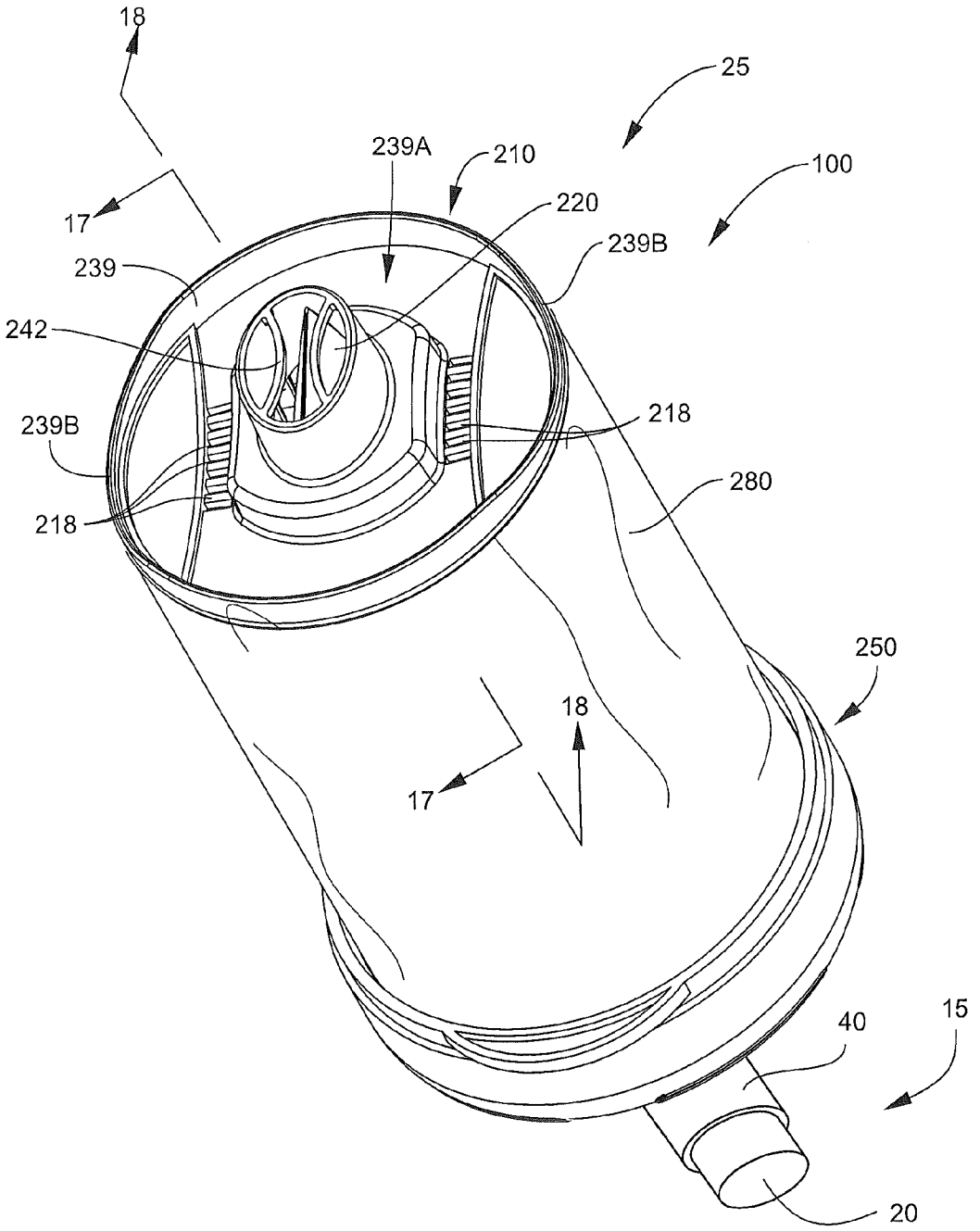
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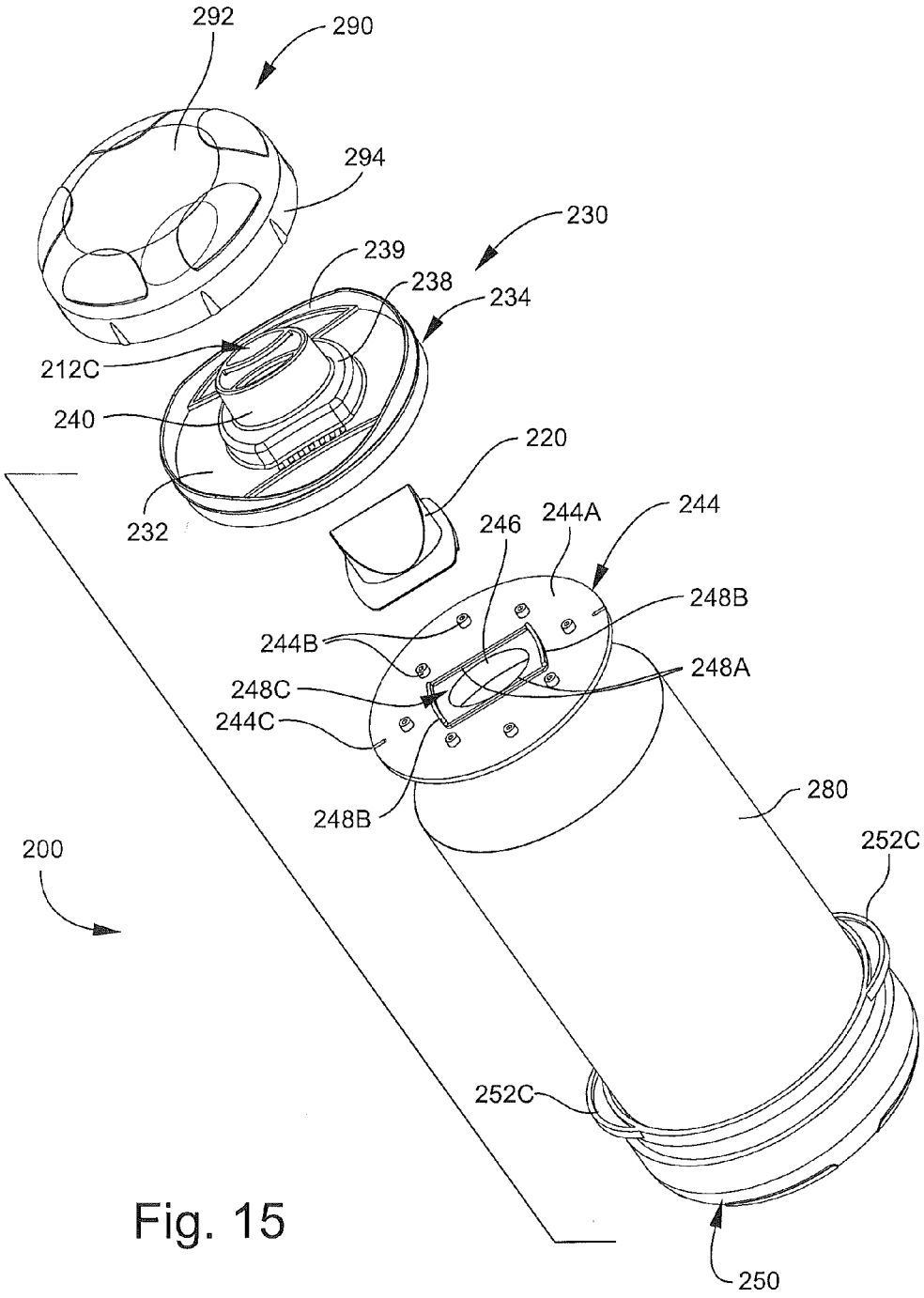
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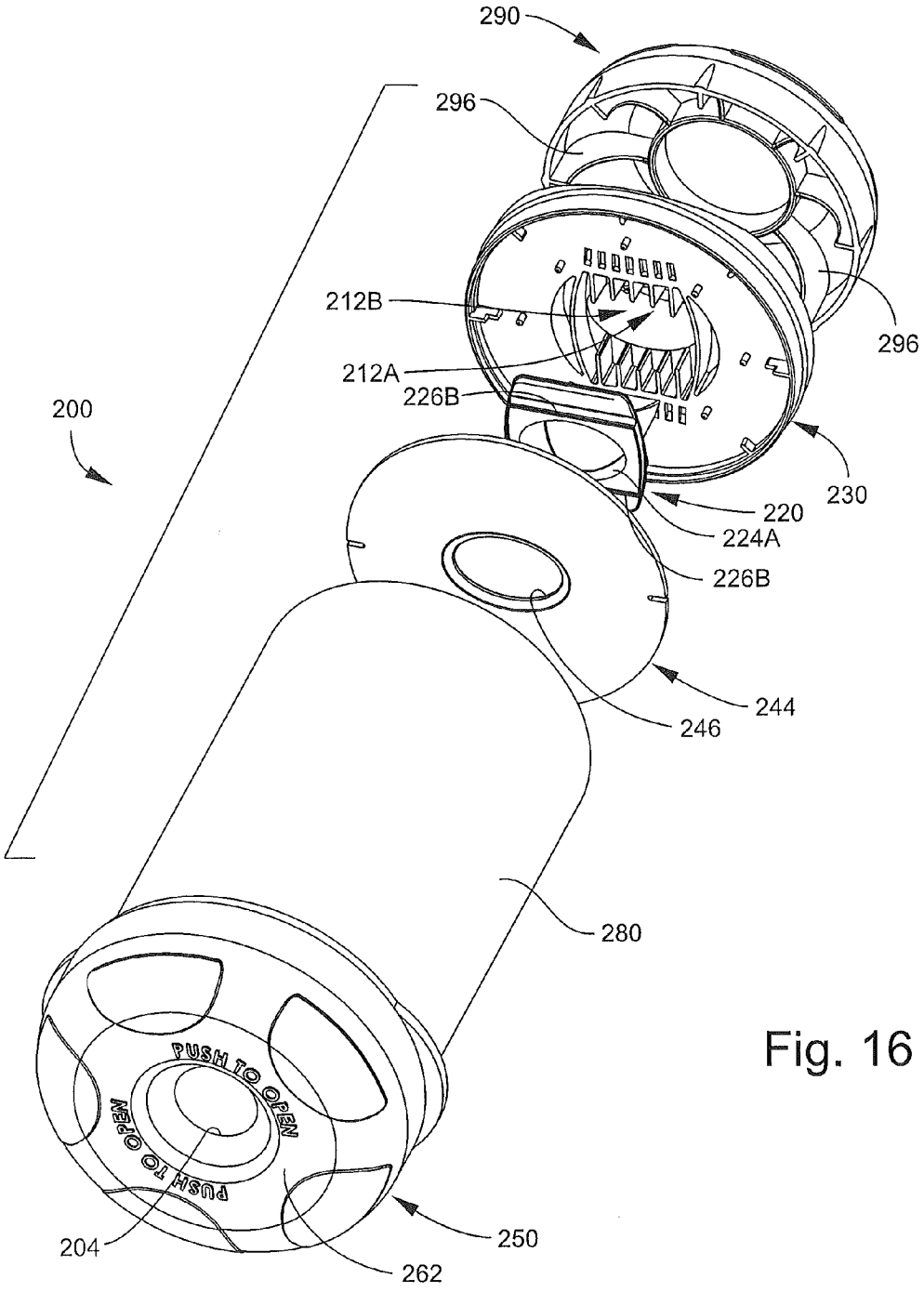
Fig. 15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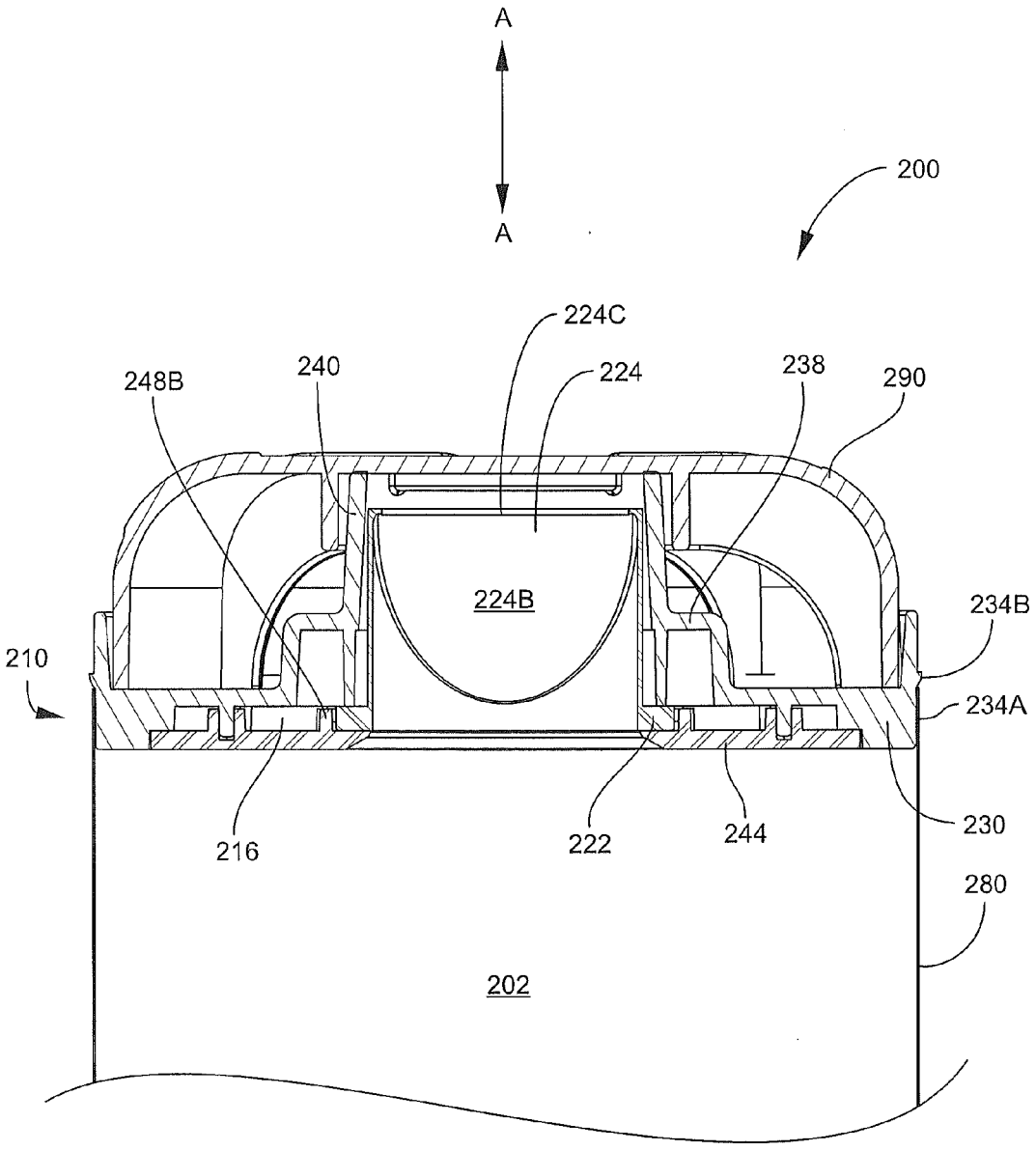
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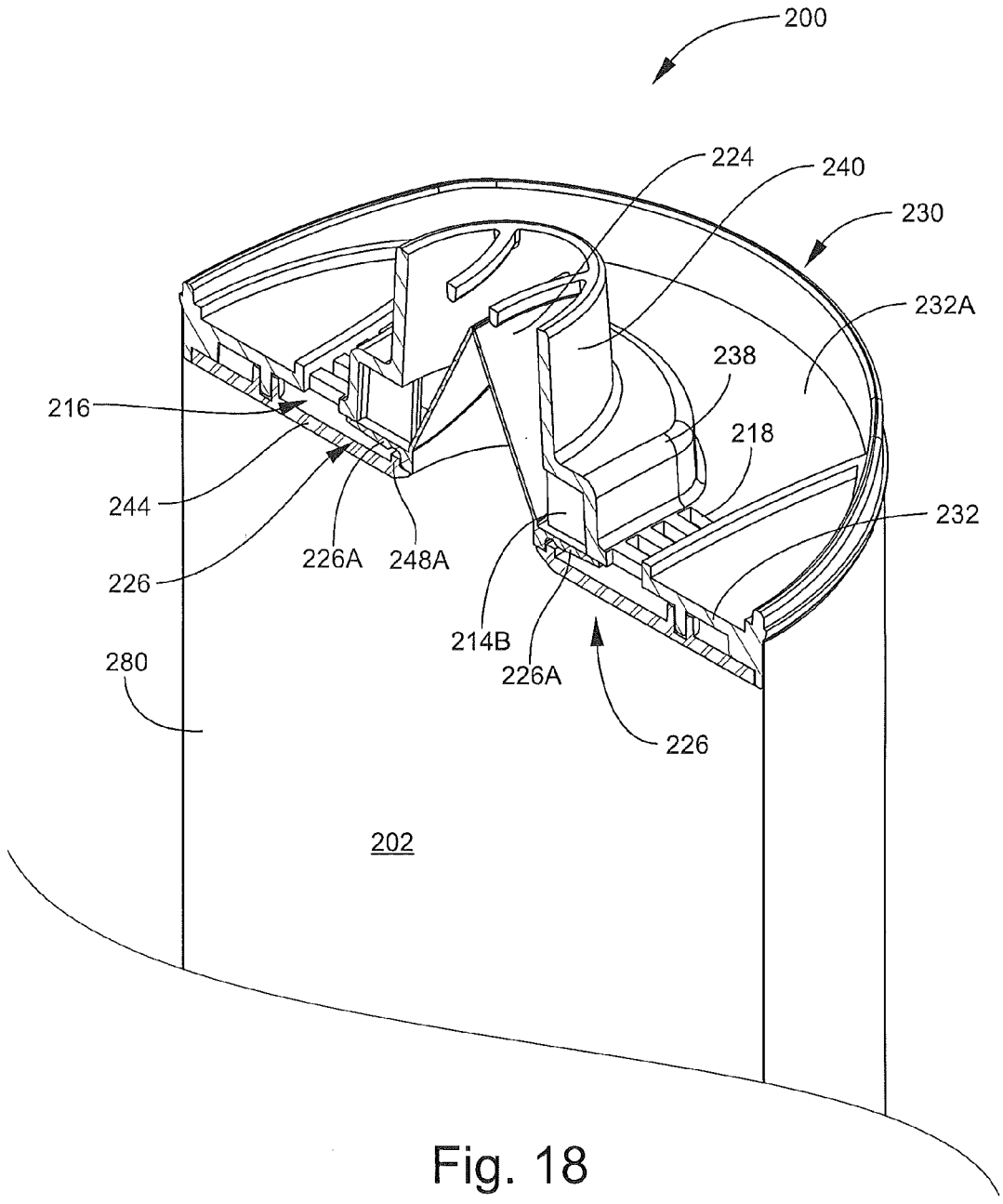
Fig. 17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232
214B
226A
226
280
202

Fig. 18

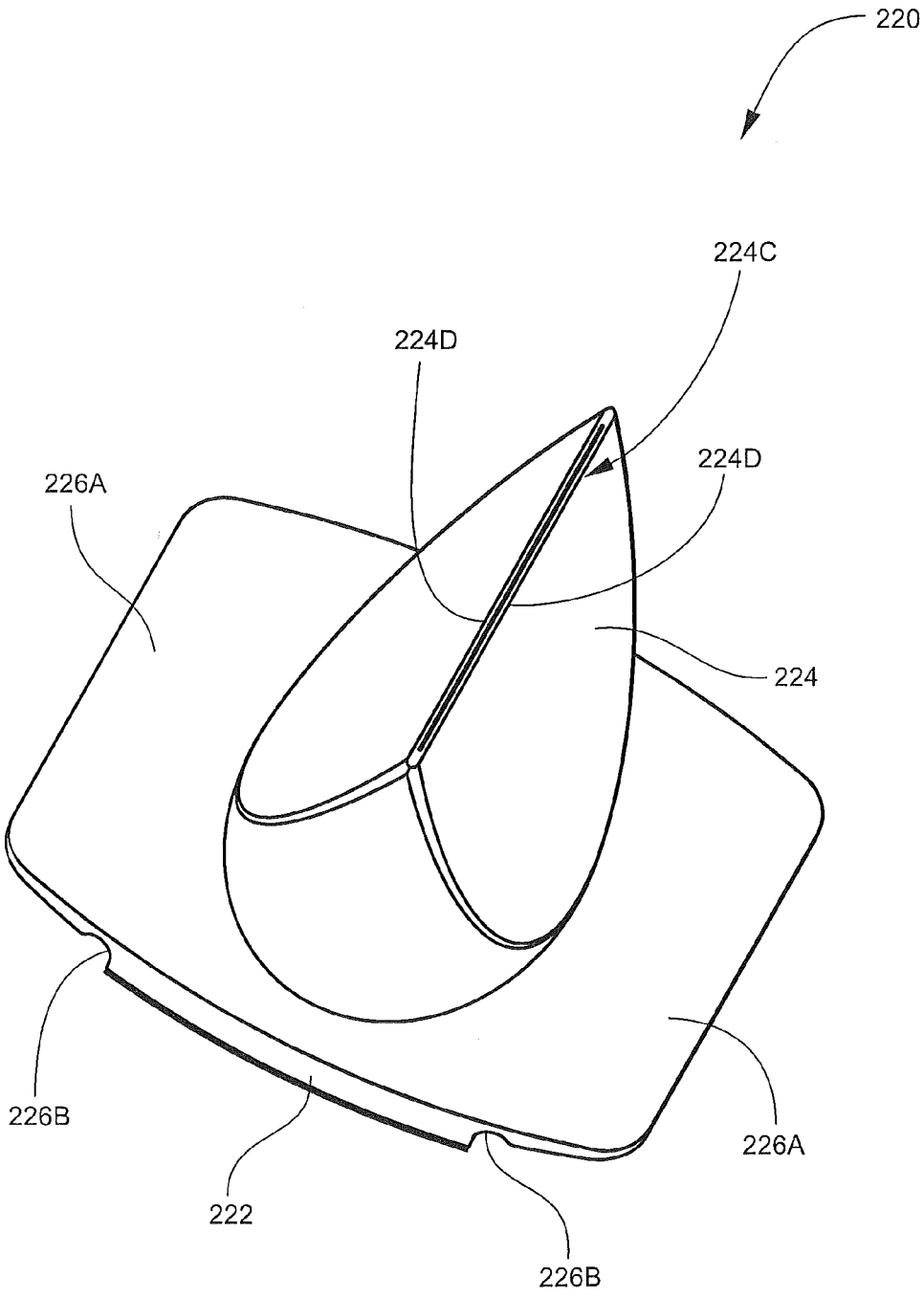

Fig. 19

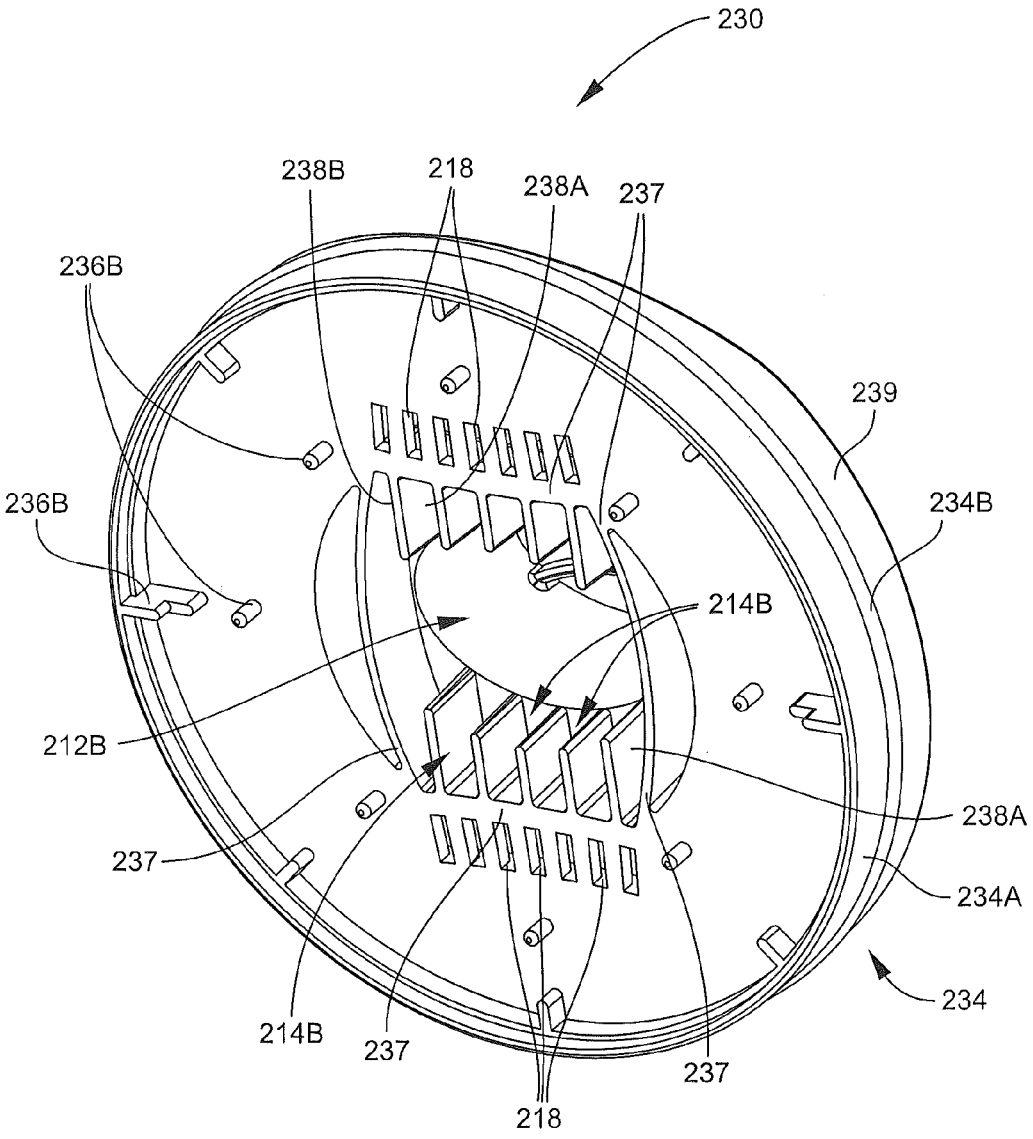
230
238B
218
238A
237
236B
239
236B
234B
214B
212B
238A
237
234A
234
214B
237
237
218

Fig. 20A

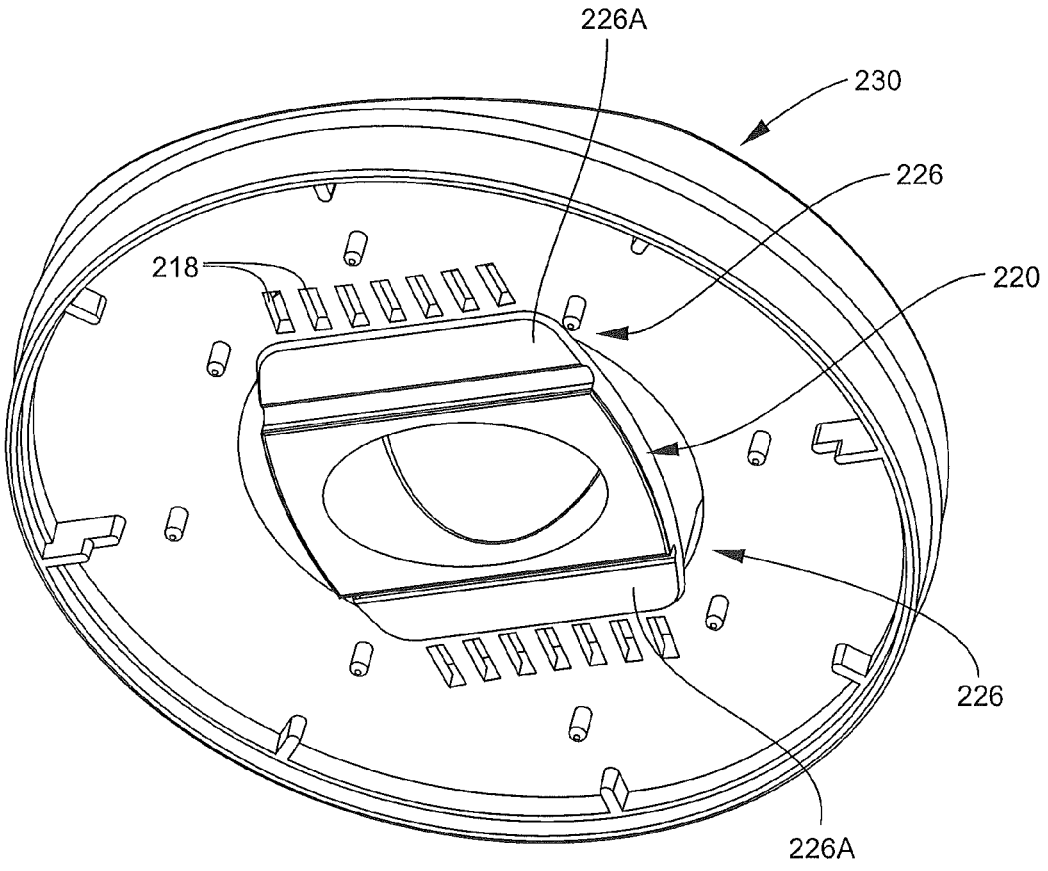

Fig. 20B

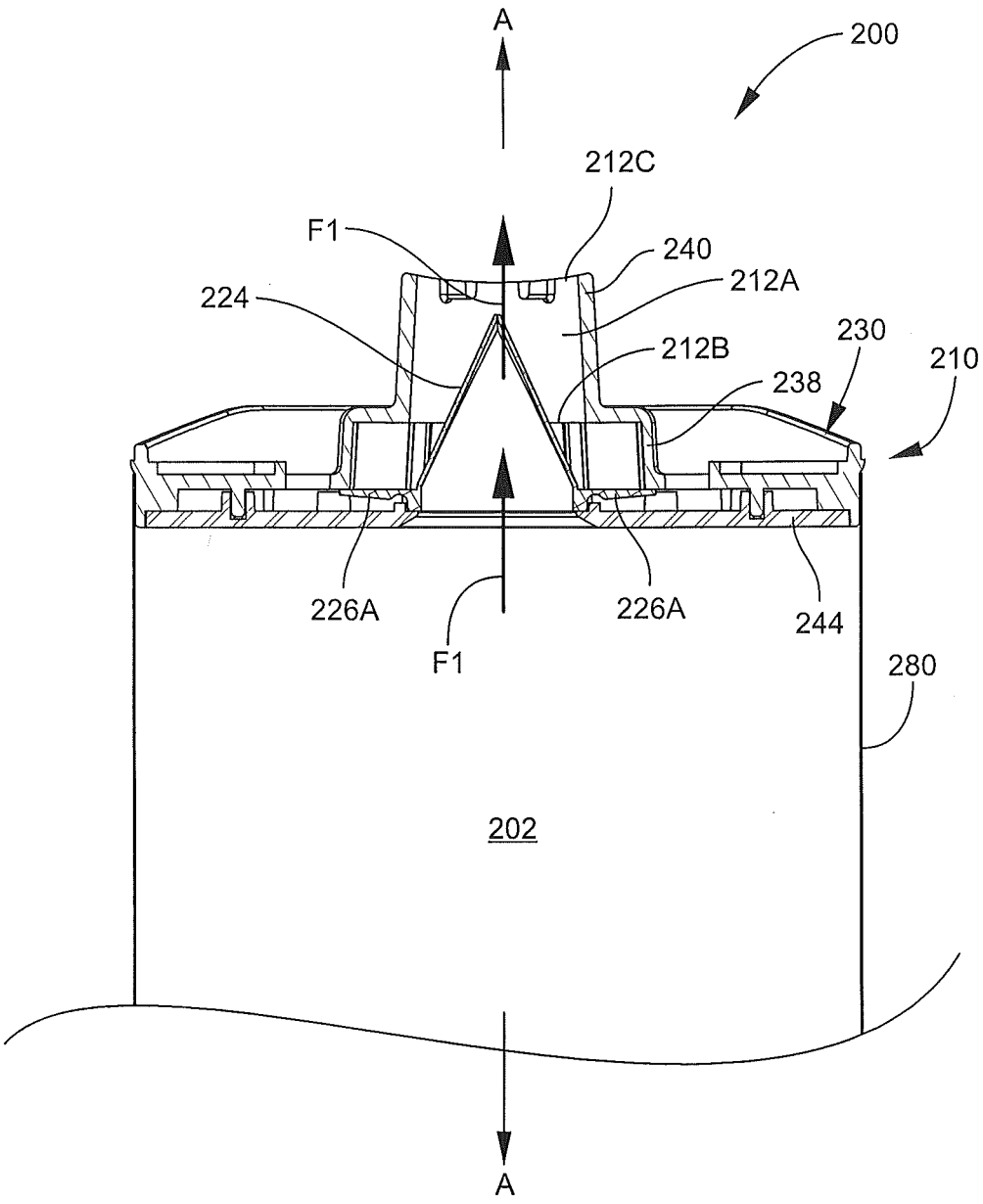
A
200
212C
F1
240
212A
224
230
212B
210
238
226A
226A
244
F1
280
202
A

Fig. 21

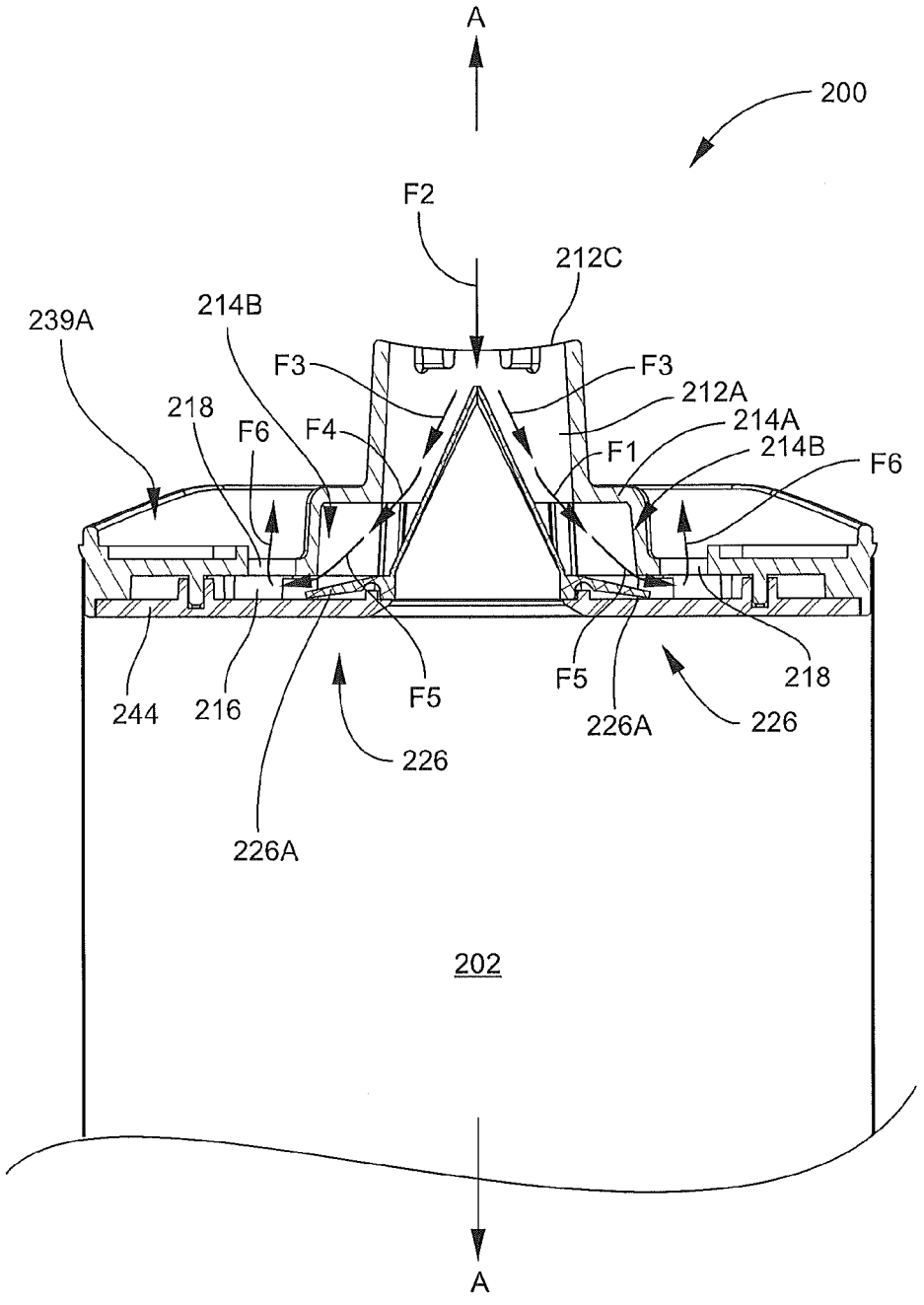
A
200
F2
212C
214B
239A
F3
F3
212A
218
F6
F4
214A
F1
214B
F6
244
216
F5
F5
218
226A
226
226
226A
202
A

Fig. 22

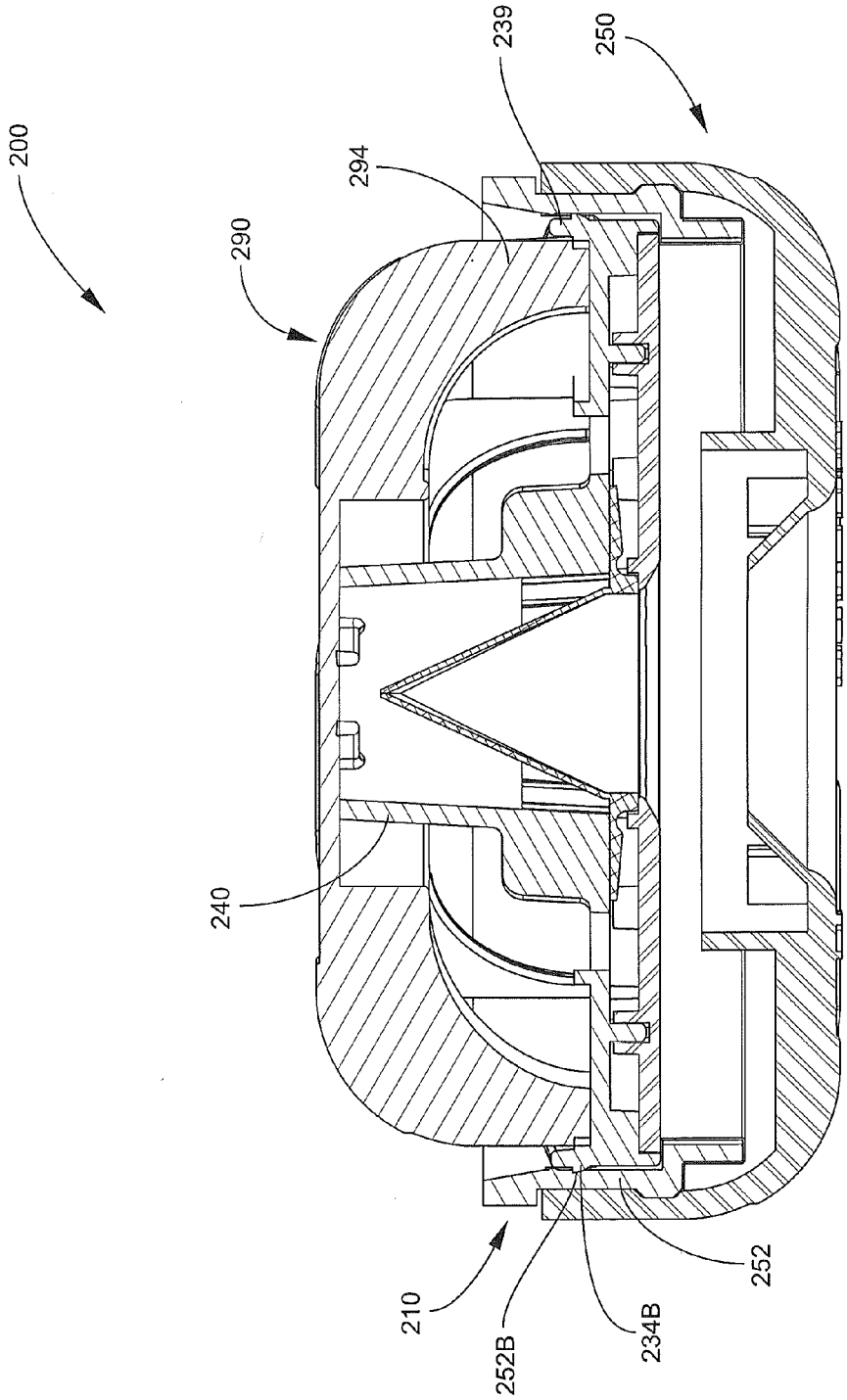

Fig. 23

INHALATION DEVICES AND SYSTEMS AND METHODS INCLUDING THE SAME

RELATED APPLICATION(S)

This application claims the benefit of and priority from U.S. Provisional Patent Application No. 61/771,406, filed Mar. 1, 2013, and U.S. Provisional Patent Application No. 61/636,320, filed Apr. 20, 2012, the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to inhalation devices and, more particularly, to inhalation devices and systems and methods including the same for delivering a dispersed dose of a medication for inhalation by a patient.

BACKGROUND OF THE INVENTION

Oronasal delivery of drugs has long been known and has gained wide acceptance. Pharmaceuticals for the treatment of tracheal, bronchial, nasal and pulmonary conditions are widely available in prescribed or metered doses in small pressurized aerosol canisters. While medications can be dispensed directly from such canisters into the oronasal passages of patients, experience has proven that patients generally have not made optimum use of and/or have not obtained optimum benefits from medications delivered directly from the aerosol canisters.

Because direct use of the aerosol canisters has not proven effective or efficient for a large proportion of patients, many devices have been proposed for converting the medications from the concentrated pressurized form in which they are discharged from aerosol canisters into a nonpressurized and less concentrated form in order to be more readily and efficaciously inhaled by the patient. Further, it has been found that a long and slow inspiration of the medication promotes a highly efficient distribution of medication to partially occluded airways. Thus, it is desirable in such devices to inhibit rapid inhalation and to encourage a long and slow inspiration period.

In order to promote a long and slow inspiration period, it is desirable to provide an expandable breathing bag or spacer, so that the patient is required during respiratory maneuvers to utilize a negative thoracic pressure upon inhalation, thereby to inhibit rapid inhalation and encourage long and slow inhalation. Representative prior art devices having expandable and contractible breathing bags or spacer chambers may be found by way of example, in U.S. Pat. No. 4,938,210 to Shene, U.S. Pat. No. 4,940,051 to Lankinen, U.S. Pat. No. 5,040,527 to Larson et al., U.S. Pat. No. 4,484,577 to Sackner et al., and U.S. Pat. No. 5,318,016 to Mecikalski.

SUMMARY OF THE INVENTION

According to embodiments of the present invention, a collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser, the MDI dispenser operable to dispense a dose of a medication therefrom, includes an outlet end member, an inlet end member and a tubular, pliable, collapsible sleeve member. The outlet end member includes a mouthpiece. The inlet end member includes an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser. The sleeve member has first and second opposed ends attached to the inlet end member and the outlet end member, respectively. The inhalation device is positionable in each of an open position, wherein the outlet end member and the inlet end member are spaced apart and the sleeve member is extended such that the outlet end member, the inlet end member and the sleeve member define a chamber, and a closed position, wherein the sleeve member is collapsed and the outlet end member and the inlet end member are proximate one another and envelope the sleeve member. When the inhalation device is in the open position with the MDI dispenser mounted in the MDI dispenser mount structure, a dose of the medication can be dispensed from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece.

In some embodiments, the MDI dispenser includes an MDI aerosol canister mounted in an MDI holder having a dispensing section, and the inlet port and the MDI dispenser mount structure are configured to receive and engage the dispensing section such that the dispensing section extends through the inlet port.

The outlet end member may include a one-way inhalation valve that enables outflow of air from the chamber through the mouthpiece and prevents inflow of air into the chamber through the mouthpiece. In some embodiments, the mouthpiece further includes a one-way blowback relief valve that enables outflow of air from the mouthpiece through the one-way blowback relief valve and prevents inflow of air into the mouthpiece through the one-way blowback relief valve. The mouthpiece can include a trap structure configured to catch and prevent a component of the one-way inhalation valve from being inhaled through the mouthpiece.

In some embodiments, the sleeve member is substantially cylindrical when the inhalation device is in the open position.

The inhalation device can include a latch mechanism to releasably secure the outlet end member to the inlet end member when the inhalation device is in the closed position. The inhalation device can include at least one release tab operable by a user to actuate the latch mechanism to release the outlet end member from the inlet end member to open the inhalation device.

According to some embodiments, the inlet end member includes a ring member to which the sleeve member is affixed, and a cover member mounted on the ring member, wherein the cover member is removable from and replaceable on the ring member to provide access to the interior of the inhalation device for cleaning. In some embodiments, the cover member is formed of a first material including a resilient, deformable elastomer, and the ring member is formed of a second material more rigid than the first material.

According to some embodiments, the sleeve member is formed of a polymeric film having a thickness in the range of from about 4 to 8 mil. According to some embodiments, the polymeric film has a thickness in the range of from about 4 to 6 mil.

The sleeve member may be formed of a low density polyethylene (LDPE) film. In some embodiments, the LDPE film is an anti-static LDPE film having a surface resistivity of 1×10^{12} Ohms/square or less as measured according to ASTM D257-07.

In some embodiments, at least a portion of at least one of the outlet end member and the inlet end member is formed of a polymeric material blended and/or coated with a supplemental material that imparts an anti-static property to the polymeric material.

According to some embodiments, one of the outlet end member and the inlet end member includes an annular ring member having a radially outwardly facing outer attachment

surface and defining a through passage, wherein the sleeve member is bonded to the outer attachment surface and extends through the through passage to attach to the other of the outlet end member and the inlet end member. The sleeve member may be heat welded to the outer attachment surface.

According to some embodiments, the outlet end member includes a body and the mouthpiece is hingedly coupled to the body to rotate between an extended, deployed position and a retracted, stored position.

According to method embodiments of the present invention, a method for administering a dose of a medication to a patient from a metered dose inhaler (MDI) dispenser includes providing a collapsible inhalation device including: an outlet end member including a mouthpiece; an inlet end member including an inlet port and an MDI dispenser mount structure and configured to receive and engage the MDI dispenser; and a tubular, pliable, collapsible sleeve member having first and second opposed ends attached to the inlet end member and the outlet end member, respectively; wherein the inhalation device is positionable in each of an open position, wherein the outlet end member and the inlet end member are spaced apart and the sleeve member is extended such that the outlet end member, the inlet end member and the sleeve member define a chamber, and a closed position, wherein the sleeve member is collapsed and the outlet end member and the inlet end member are proximate one another and envelope the sleeve member. The method further includes: placing the inhalation device in the open position; mounting the MDI dispenser in the MDI dispenser mount structure; and thereafter dispensing a dose of the medication from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece.

According to embodiments of the present invention, a collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser, the MDI dispenser operable to dispense a dose of a medication therefrom, includes a rigid, unitary outlet end member, an inlet end member, and a tubular, pliable, collapsible sleeve member. The outlet end member includes a mouthpiece. The inlet end member includes an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser. The sleeve member has first and second opposed ends attached to the inlet end member and the outlet end member, respectively, to define therewith a chamber. When the MDI dispenser is mounted in the MDI dispenser mount structure, a dose of the medication can be dispensed from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece. The outlet end member further includes: a one-way inhalation valve that enables outflow of air from the chamber through the mouthpiece and prevents inflow of air into the chamber through the mouthpiece; and a one-way blowback relief valve that enables outflow of air from the mouthpiece through the one-way blowback relief valve and prevents inflow of air into the mouthpiece through the one-way blowback relief valve.

According to some embodiments, the sleeve member is formed of a polymeric film having a thickness in the range of from about 4 to 8 mil.

According to some embodiments, the outlet end member defines an exhaust port and at least one internal conduit fluidly connecting the mouthpiece to the exhaust port, and the outlet end member is configured to direct exhalation air flow from the patient through the mouthpiece, through the one-way blowback relief valve, through the at least one internal conduit, and out through the exhaust port. In some embodiments, the outlet end member includes a mouthpiece member, a backplate, and a valve member captured between the mouthpiece member and the backplate. The outlet end member and the backplate define an internal conduit in the outlet end member fluidly connecting the one-way blowback relief valve to the exhaust port. In some embodiments, the exhaust port is located on an axial end face of the outlet end member.

In some embodiments, the outlet end member includes a valve member including the one-way inhalation valve, and the one-way inhalation valve is a self-sealing valve. The one-way inhalation valve may be a duckbill valve. In some embodiments, the valve member further includes an integral, radially extending valve flap forming a part of the one-way blowback relief valve.

According to method embodiments of the present invention, a method for forming a collapsible inhalation device includes providing an end member including an annular ring member having a radially outwardly facing outer attachment surface and defining a through passage; providing a tubular, pliable, collapsible sleeve member having first and second sleeve sections; bonding the first sleeve section to the outer attachment surface; and routing the second sleeve section through the through passage.

In some embodiments, bonding the first sleeve section to the outer attachment surface includes heat welding the first sleeve section to the outer attachment surface.

The method may include inverting the sleeve member through itself and the through passage following the step of bonding the first sleeve section to the outer attachment surface.

Further features, advantages and details of the present invention will be appreciated by those of ordinary skill in the art from a reading of the figures and the detailed description of the embodiments that follow, such description being merely illustrative of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is side elevational view of an inhalation system according to embodiments of the present invention being used by a patient to administer a dose of an inhalable medication.

FIG. **2** is a front, top perspective view of a collapsible inhalation device according to embodiments of the present invention and forming a part of the inhalation system of FIG. **1**.

FIG. **3** is a bottom, rear perspective view of the inhalation device of FIG. **2**.

FIG. **4** is a top plan view of the inhalation device of FIG. **2**.

FIG. **5** is a bottom plan view of the inhalation device of FIG. **2**.

FIG. **6** is an exploded, front, top perspective view of the inhalation device of FIG. **2**.

FIG. **7** is a fragmentary, cross-sectional view of the inhalation device of FIG. **2** taken along the line **7-7** of FIG. **4**.

FIG. **8** is a front, top perspective view of the inhalation device of FIG. **2** with a mouthpiece thereof in an extended, deployed position.

FIG. **9** is an enlarged, fragmentary, cross-sectional view of the inhalation device of FIG. **2** with the mouthpiece in the extended, deployed position.

FIG. **10**A is a top perspective view of the inhalation device of FIG. **2** in a partially collapsed position.

FIG. **10**B is a front, top perspective view of the inhalation device of FIG. **2** in a closed position.

FIGS. **11**A and **11**B illustrate methods for constructing the inhalation device of FIG. **2**.

FIG. **12** is an enlarged, fragmentary, cross-sectional view of the inhalation system of FIG. **1**.

FIG. **13** is a front, top perspective view of a collapsible inhalation device according to further embodiments of the present invention.

FIG. **14** is a front, top perspective view of an inhalation system including the inhalation device of FIG. **13**.

FIG. **15** is an exploded, front, top perspective view of the inhalation device of FIG. **13**.

FIG. **16** is an exploded, rear, bottom perspective view of the inhalation device of FIG. **13**.

FIG. **17** is a fragmentary, cross-sectional view of the inhalation device of FIG. **13** taken along the line **17-17** of FIG. **14**.

FIG. **18** is a fragmentary, perspective, cross-sectional view of the inhalation device of FIG. **13** taken along the line **18-18** of FIG. **14**.

FIG. **19** is a top perspective view of a valve member forming a part of the inhalation device of FIG. **13**.

FIG. **20**A is a bottom perspective view of a mouthpiece member forming a part of the inhalation device of FIG. **13**.

FIG. **20**B is a bottom perspective view of the mouthpiece member of FIG. **20**A with the valve member mounted therein.

FIG. **21** is a fragmentary, cross-sectional view of the inhalation device of FIG. **13** taken along the line **18-18** of FIG. **14** illustrating an inhalation flow through the inhalation device.

FIG. **22** is a fragmentary, cross-sectional view of the inhalation device of FIG. **13** taken along the line **18-18** of FIG. **14** illustrating an exhalation flow through the inhalation device.

FIG. **23** is a cross-sectional view of the inhalation device of FIG. **13** in a closed, collapsed position.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which illustrative embodiments of the invention are shown. In the drawings, the relative sizes of regions or features may be exaggerated for clarity. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

It will be understood that when an element is referred to as being "coupled" or "connected" to another element, it can be directly coupled or connected to the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly coupled" or "directly connected" to another element, there are no intervening elements present. Like numbers refer to like elements throughout.

In addition, spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is turned over, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein the expression "and/or" includes any and all combinations of one or more of the associated listed items.

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

As used herein, "monolithic" means an object that is a single, unitary piece formed or composed of a material without joints or seams.

Embodiments of the present invention can provide inhalation devices or so-called spacers for administering oral nasal medications. The inhalation devices can convert medications for treatment of tracheal, bronchial, nasal and pulmonary conditions from a concentrated pressurized aerosol form into a nonpressurized, air diluted form for ease and greater efficacy of inhalation by a patient suffering from such a condition.

With reference to FIGS. **1-12**, an inhalation device or spacer **100** according to embodiments of the present invention is shown therein. The inhalation device **100** may be used in conjunction with an inhalable medication dispenser **15** (FIGS. **1** and **12**), for example, to form an inhalation system **10** to deliver medication from the dispenser **15** in an air diluted and nonpressurized form to the oronasal breathing passages of a human patient P. According to some embodiments and as illustrated in FIG. **12**, the dispenser **15** can be actuated to inject a prescribed or predetermined metered dose D of the medication into a chamber **102** defined by the inhalation device **100**, where the medication dose is mixed with air in the chamber **102** to form a dispersed, gaseous medicine mixture M. A patient P can then inhale the mixture M from the inhalation device **100** through a mouthpiece **136** of the inhalation device **100**.

The inhalation device **100** can be adapted or configured to effectively receive and engage inhalable medication dispensers of a variety of form factors including conventional dispensers comprising a metered dose inhaler (MDI) aerosol canister mounted in an L-shaped holder of the type commonly referred to as a boot. As a result, the inhalation device **100** can enable the user to effectively use features and benefits attendant to the dispenser itself. In particular, according to some embodiments, the dispenser **15** includes an integral dose counter **50** (FIG. **12**) that maintains a running count of the number of doses D that have been dispensed therefrom.

Advantageously, the inhalation device **100** can be collapsed into a relatively compact form factor when not in use, as shown in FIG. **10**B. Further advantages and aspects of

inhalation devices and spacers according to embodiments of the present invention will be apparent from the description that follows.

The medicine dispensed from the dispenser **15** may be any suitable medicine for oronasal delivery. According to some embodiments, the medicine is delivered as a fine powder. According to some embodiments, the medicine is delivered as fine liquid droplets.

As discussed above and with reference to FIG. **12**, the dispenser **15** may include a metered dose inhaler (MDI) unit **20** and a holder or boot **40**. The MDI unit **20** may be of any suitable construction, including MDI units of conventional and well-known designs. According to some embodiments, the MDI unit **20** includes an aerosol canister **22** and a dispensing nozzle **24**. As is well-known, the contents of the canister **22** (i.e., the medication) are under pressure substantially greater than ambient and can be dispensed by depressing the nozzle **24**. Typically, the actuator of the MDI unit **20** is configured so that with each depression, the nozzle **24** will cause the MDI unit **20** to dispense or eject a metered, predetermined amount of the medication (i.e., the predetermined dose). Suitable MDI units may include ProAir® HFA (albuterol sulfate), Symbicort® (budesonide/formoterol fumarate dihydrate; includes counter), Advair® HFA (fluticasone propionate and salmeterol; includes counter), and Proventil® HFA (albuterol sulfate).

The MDI unit holder **40** may be of any suitable construction, including holders or boots of conventional and well-known designs. According to some embodiments, the boot **40** includes a body **42** having a canister section **44** and a dispensing section **46**. The canister section **44** defines a cavity **44**A to hold the canister **22**. The dispensing section **46** defines a dispensing passage **46**A terminating at an exit opening **46**B. An actuator, which may be integrally molded with the sections **44**, **46**, is provided between the cavity **44**A and the passage **46**A. The counter device **50** has a display **50**A and is also mounted in the body **42**. The body **42** includes a window opening **44**B to enable a user to view the display **50**A. A protective end cap **46**C may be provided to selectively fit over and seal the opening **46**B. Suitable holders may include those provided with ProAir® HFA (albuterol sulfate), Symbicort® (budesonide/formoterol fumarate dihydrate; includes counter), Advair® HFA (fluticasone propionate and salmeterol; includes counter), and Proventil® HFA (albuterol sulfate). The counter device **50** may include a transducer that generates a signal responsive to a predetermined pressure change or level (i.e., corresponding to an actuation of the MDI unit **20**), and a controller (e.g., an integrated circuit) that processes the signal and generates a count display on the display **50**A. Other suitable counters may be fully or partially mechanical counters.

With reference to FIGS. **2-7**, the inhalation device **100** has a longitudinal axis A-A (FIG. **1**) and includes an outlet end member **110** (hereinafter, the head **110**), an inlet end member **150** (hereinafter, the base **150**), and a pliable, flexible bag or sleeve member **180**. The head **110**, the base **150**, and the sleeve member **180** collectively define the chamber **102**. The base **150** includes an inlet opening or aerosol injection port **104** communicating with the chamber **102**. The mouthpiece **136** forms a part of the head **110** and defines an outlet opening **136**B (FIG. **7**) selectively communicating with the chamber **102** when the mouthpiece **136** is deployed.

Turning to the head **110** in more detail, the head **110** includes a body **112** (FIG. **2**). The body **112** has an end wall **114** and an integral sidewall **116**. An opening **120** (FIGS. **3** and **7**) is defined in the end wall **114** for outflow of air or mixture M from the chamber **102**. As shown in FIG. **6**, the sidewall **116** includes an annular upper sidewall section **116**A contiguous with the end wall **114**, an annular attachment flange **116**B depending from the upper sidewall section **116**A, and an annular bead or rib **116**C extending along the interface between the section **116**A and the flange **116**B. An upstanding, annular guide wall **132** (FIG. **6**) surrounds the opening **120**.

A one-way inhalation valve **122** (FIG. **7**) is located across the opening **120** and configured to permit the air or mixture M to flow out of the chamber **102** through the opening **120** while preventing air, debris or the like from being displaced, forced or drawn into the chamber **102** through the opening **120**. The valve **122** can also prevent or inhibit air and medication from escaping the chamber **102** prior to inhalation. More particularly, the valve **122** includes a valve member, diaphragm or flap **122**A (FIGS. **4** and **6**) secured to the end wall **114** by anchors **122**C (e.g., heat stakes; FIG. **6**) and limited by stop bars **122**B (FIG. **3**).

The mouthpiece **136** defines a through passage **137** (FIG. **7**) terminating at an inlet opening **136**A and an opposed outlet opening **136**B. A trap structure, filter or grill **138** may be provided in the passage (e.g., at or proximate the outlet opening **136**B). The trap structure **138** may serve to inhibit or prevent the entry of foreign objects or debris into the mouthpiece **136** as well as to ensure that the valve flap **122**A, if it were to become detached from the end wall **114**, is not inhale by the patient. Grip grooves **144** (FIG. **6**) or the like may be provided to facilitate manipulation of the mouthpiece **136**.

The mouthpiece **136** is foldable about the hinge between a stored position as shown in FIG. **2** and an operative or deployed position as shown in FIGS. **1**, **8** and **9**. The end wall **114** defines a mouthpiece recess **124** (FIG. **8**) within which the mouthpiece **136** resides when in the stored position to provide a low profile. The mouthpiece **136** is pivotally coupled to the end wall **114** by hinge projections **142** that rotatably seat in holes or detents **126** (FIG. **6**). Latch features may be provided to releasably secure the mouthpiece **136** in the stored and/or the deployed position. For example, a front latch tab **128** is provided to releasably engage the front end of the mouthpiece **136** to hold the mouthpiece **136** in the stored position as shown in FIG. **7**. A rear latch tab **140** on the mouthpiece **136** is provided to releasably engage a latch feature in the form of a detent **130** on the end wall **114** when the mouthpiece **136** is in the extended position of FIG. **9**.

The mouthpiece **136** may also be provided with a one-way exhalation or blowback relief valve **139** (FIGS. **7** and **8**). The valve **139** includes an upstanding annular wall **139**A on the lower side of the mouthpiece **136**. The wall **139**A defines a cavity **139**B communicating with a valve opening **139**E extending through the mouthpiece **136**. Stop bars **139**C extend across the opening **136**E and support a mounting post **139**D. A valve member, diaphragm or flap **139**F is mounted on and affixed to (e.g., by heat staking) the post **139**D on the outer side of the stop bars **139**C. The flap **139**F is recessed to prevent removal. The valve **139** is thus configured to permit flow of pressurized air out of the mouthpiece **136** through the opening **139**E while preventing inflow through the opening **139**E. A recess **115** is provided in the end wall **114** to receive all or a portion of the valve **139** when the mouthpiece **136** is in the retracted position.

Turning to the base **150** in more detail, the base **150** includes an annular ring member **152** and a cover member **160**. The cover member **160** may be detachably and re-attachably secured to the ring member **152**.

Referring to FIG. **7**, the ring member **152** includes an annular upper section **154** and an annular attachment flange **156** that collectively define an inner passage **152**A. An annu-

lar outer coupling rib **154**A extends radially outwardly from the upper section **154**. The attachment flange **156** has an outer surface **156**A. The ring member **152** further includes one or more annular latch grooves **1528** defined in the inner diameter surface thereof and opposed release tabs **152**C (FIG. **4**) extending radially outwardly at or proximate the top edge of the ring member **152**.

The cover member **160** (FIG. **7**) includes an end wall **162** and an annular sidewall **164** depending therefrom. An annular inner coupling groove **164**A is defined in the sidewall **164** and positioned and configured to mate with the coupling rib **154**A. The cover member **160** includes a dispenser mount structure **165** including a deformable, resilient sealing flange **166** extending axially inwardly from the end wall **162**. The inner, distal edge of the sealing flange **166** defines the inlet opening **104**. The sealing flange **166** and the inlet opening **104** are sized and shaped to receive and hold the dispensing section **46** of the holder **40**. According to some embodiments, the mount structure **165** is configured such that the section **46** can be inserted into the inlet opening **104** without requiring undue force but, once installed, will resist inadvertent or non-deliberate forces tending to withdraw the holder **40** from the cover member **160**. According to some embodiments and as shown, the sealing flange **166** is frusto-conical and tapers radially inwardly as the sealing flange **166** extends further into the chamber **102**. A reinforcement wall **168** (FIG. **2**) and ribs **168**A may be provided to reinforce the end wall **162** and the sealing flange **166**. The cover member **160** further includes indicia **172** (FIG. **3**). According to some embodiments, the cover member **160**, when mounted on the ring member **152**, provides a substantially airtight seal therebetween (FIG. **2**).

The sleeve member **180** is continuous, tubular and open at either end. The sleeve member **180** is formed of a flexible, pliable, collapsible film or layer and, according to some embodiments, a polymeric film layer. With reference to FIG. **7**, the sleeve member **180** includes a base attachment section **182**, a transitional section **183**, a main section **184**, and a head attachment section **186**. The base attachment section **182** is attached to the ring member **152** and the head attachment section **186** is attached to the head body **112** as discussed in more detail below. The transitional section **183** provides a transition between the base attachment section **182** and the main section **184**. The main section **184** defines, in part, the chamber **102**. According to some embodiments, when the device **100** is in the open position, the sleeve member **180** is substantially cylindrical.

According to some embodiments and with reference to FIGS. **7**, **11**A and **11**B, the sleeve member **180** is secured to the base **150** using the following inventive method. The base attachment section **182** is placed around and bonded to the outer surface **156**A of the attachment flange **156** of the ring member **152**. The outer coupling rib **154**A can be used to locate the terminal edge of the sleeve member **180**. According to some embodiments, the section **182** is heat welded to the surface **156**A. The sleeve member **180** is then inverted through itself and the inner passage **152**A of the ring member **152** as shown in FIG. **11**B such that the transitional section **183** wraps around the ring member **152**.

The head attachment section **186** of the sleeve member **180** can then be placed around and bonded to the outer surface of the attachment flange **116**B of the head **110**. The annular rib **116**C can be used to locate the terminal edge of the sleeve member **180**.

According to some embodiments, the annular seals formed between the sleeve member **180** and the attachment flange **156** and between the sleeve member **180** and the attachment flange **116**B are substantially airtight.

The annular seals may be formed between the sleeve member **180** and the attachment flange **156** and the attachment flange **116**B by techniques other than or in addition to heat welding, such as using adhesive.

Assembly of the inhalation device **100** can further include mounting the valve flap **122**A on the body **112** by any suitable method such as heat staking. The mouthpiece **136** is mounted on the body **112** by pushing the hinge projections **142** down until they snap into engagement with the holes **126**. The base **150** is completed by pushing the cover member **160** onto the ring member **152** such that the coupling rib **154**A seats in the groove **164**A.

According to some embodiments, the device **100** could be sterilized by any suitable method following assembly.

The sleeve member **180** is formed of a flexible plastic tube or sheet material. According to some embodiments, the sleeve material is durable and air impervious. According to some embodiments, the sleeve member **180** is formed of a polymeric material which can include an anti-static component. According to some embodiments, the sleeve member **180** is formed of a polymeric film having a thickness in the range of from about 4 to 8 mil. According to some embodiments, the sleeve member **180** is formed of a polymeric film having a thickness in the range of from about 4 to 6 mil.

According to some embodiments, the sleeve member **180** is formed of low density polyethylene (LDPE). According to some embodiments, the sleeve member **180** is formed of LDPE loaded, blended, mixed or coated with a supplemental material that enhances the anti-static properties of the LDPE, such as an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™)

According to some embodiments, the sleeve member **180** is formed of material (e.g., LDPE with anti-static enhancement) having a surface resistivity of 1×10^{12} Ohms/square or less as measured according to ASTM D257-07 (*Standard Test Methods for DC Resistance or Conductance of Insulating Materials*) and, according to some embodiments, of between 1×10^{9} and 1×10^{12} Ohms/square according to ASTM D257-07.

The body **112** of the head **110** can be formed of any suitable material. According to some embodiments, the body **112** is unitarily molded. According to some embodiments, the body **112** is formed of a rigid or semi-rigid polymeric material. According to some embodiments, the body **112** is formed of high density polyethylene (HDPE). According to some embodiments, the head **110** is formed of polymer loaded, blended, mixed or coated with a supplemental material that enhances the anti-static properties of the polymer, such as an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™).

The mouthpiece **136** can be formed of any suitable material. According to some embodiments, the mouthpiece **136** is unitarily molded. According to some embodiments, the mouthpiece **136** is formed of a rigid or semi-rigid polymeric material. According to some embodiments, the mouthpiece **136** is formed of HDPE.

The valve flaps **122**A, **139**F can be formed of any suitable flexible, resilient material. According to some embodiments, the valve flaps **122**A, **139**F are unitarily molded. According to some embodiments, the valve flaps **122**A, **139**F are formed of TPE or silicone rubber.

The ring member **152** of the base **150** can be formed of any suitable material. According to some embodiments, the ring member **152** is unitarily molded. According to some embodiments, the ring member **152** is formed of a rigid or semi-rigid polymeric material. According to some embodiments, the ring member **152** is formed of HDPE. According to some

embodiments, the ring member **152** is formed of polymer loaded, mixed or coated with a supplemental material that enhances the anti-static properties of the polymer, such as an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™).

The cover member **160** can be formed of any suitable material. According to some embodiments, the cover member **160** is unitarily molded. According to some embodiments, the cover member **160** is formed of a material that is less rigid and/or less hard than the ring member **152**. According to some embodiments, the cover member **160** is formed of an elastomeric material. According to some embodiments, the cover member **160** is formed of a thermoplastic elastomer (TPE) or silicone. According to some embodiments, the cover member **160** is formed of an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™), or equivalent. According to some embodiments, the cover member **160** is formed of silicone rubber. According to some embodiments, the cover member **160** is formed of an elastomer loaded, blended, mixed or coated with a supplemental material that enhances the anti-static properties of the elastomer, such as an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™) or equivalent.

According to some embodiments, each of the foregoing components may be formed a material or materials that can be easily and readily sterilized by conventional techniques without destroying the device **100** or rendering the device **100** unsuitable for further use.

According to some embodiments, the length L**1** (FIG. **1**) of the inhalation device **100** when in the open position with the mouthpiece **136** deployed as shown in FIG. **1** is in the range of from about 4 to 10 inches and, according to some embodiments in the range of from about 6 to 6.4 inches. According to some embodiments, the length L**2** (FIG. **1**) from the end wall **114** to the end wall **162** when the inhalation device **100** is in the open position in the range of from about 4 to 9 inches and, according to some embodiments in the range of from about 5 to 5.4 inches.

According to some embodiments, the total thickness or length L**3** (FIG. **10**B) of the inhalation device **100** when in the closed position with the mouthpiece **136** stored as shown in FIG. **10** is in the range of from about 1.0 to 3.0 inches and, according to some embodiments in the range of from about 1.45 to 1.55 inches.

According to some embodiments, the outer diameter D**1** (FIG. **4**) of the inhalation device **100** is in the range of from about 2 to 5 inches and, according to some embodiments in the range of from about 2.8 to 3.5 inches.

According to some embodiments, the volume of the chamber **102** of the inhalation device **100** when the device **100** is fully open is in the range of from about 200 to 800 ml and, according to some embodiments in the range of from about 375 to 410 ml.

The inhalation system **10** may be used as follows according to methods of the present invention. Initially, the inhalation device **100** may be placed in the closed position of FIG. **10**B so that it is compact for transport, storage or the like. With the device **100** in the open position and the dispenser **15** removed from the device **100**, the user pushes the head **110** and the base **150** axially together such that the sleeve member **180** is captured therebetween and enveloped by the components **110**, **150**. According to some embodiments, the sleeve member **180** is fully enveloped by the head **110** and the base **150** in the closed position. According to some embodiments, the user may twist or rotate the head **110** and the base **150** relative to one another about the lengthwise axis as the user axially converges the head **110** and the base **150** in order to provide a helical lay or fold of the sleeve member **180** into the cavity defined between the head **110** and the base **150** when the device is in the closed position. The sleeve member **180** may have a configuration or material memory tending to direct the sleeve member **180** to follow the helical path or fold pattern. FIG. **10**A shows the inhalation device **100** in a partially closed, collapsed or compressed position. The head **110** and the base **150** are pushed together until the annular rib **116**C of the head **110** seats in and interlocks with the latch groove **152**B in the interior surface of the ring member **152** to releasably retain the device **100** in the closed position. The mouthpiece **136** is folded down and latched in its stored position by engagement between the latch tab **128** and the front edge of the mouthpiece **136**.

When the user desires to administer a dose of the medication from the MDI unit **20**, the user may prepare the dispenser **15** as needed. For example, the user may shake the dispenser **15** and remove the cap **46**C from the dispensing section **46**.

To open the inhalation device **100**, the user may press the tabs **152**C axially away from the head **110** while pushing the end wall **162** of the base **150** toward the head **110**. For example, the user may push forwardly on the end wall **162** with her thumbs while simultaneously pulling rearwardly on the tabs **152**C with her fingers (or the placements and motions of the thumb and fingers may be reversed). In doing so, the user deflects or warps the ring member **152** to loosen or release the engagement between the coupling features **152**B, **116**C while simultaneously pushing the head **110** out from the base **150**. With the head **110** and base **150** now disengaged, the user can pull the head **110** and base **150** away from one another along the longitudinal axis A-A to expand the sleeve member **180** into the deployed position of FIG. **2**, thereby drawing a volume of air into the chamber **102**. The mouthpiece **136** is folded out into the deployed position (FIG. **8**), including forcing the mouthpiece **136** out of engagement between the latch tab **128**, and further forcing the latch features **130** and **140** into engagement. Other methods or mechanisms may be used and provided for retaining the mouthpiece **136** in the open and closed positions.

The dispensing section **46** of the dispenser **15** is forced into the port **104** as shown in FIG. **12**. The elastomeric sealing flange **166** grips the dispensing section **46** to hold the dispenser **15** in place on the base **150**. According to some embodiments, the sealing flange **166** forms an airtight or highly air flow restricted seal about the dispensing section **46**.

The patient P places the mouthpiece **136** in her mouth (as shown in FIG. **1**; for example) and depresses the aerosol canister **22** to discharge and inject the dose D of medication into the chamber **102** through the dispensing section **46**. The device **100** may be otherwise oriented. For example, the device **100** may be rotated 180 degrees about its lengthwise axis as compared to the position shown in FIG. **1**. The dose D mixes with the air in the chamber **102** and is dispersed into a nonconcentrated or dilute dispersion suspended in the air as an air and medication mixture M. The gaseous pressure under which the medication was stored in the canister **22** is dissipated in the chamber **102** and the medication is dispersed in nonpressurized form (i.e., at ambient pressure). The one-way valve **122** is closed by default and may serve to prevent the premature escape of the dose D or the mixture M from the chamber **102** and to prevent the patient from exhaling into the chamber **102**.

With the inhalation device **100** charged with the mixture M as described above, the patient P can slowly inhale the mixture M from the device **100** through the mouthpiece **136** into the patient's breathing passages and lungs. As the air volume is inhaled from the chamber **102**, ambient air is drawn into the

chamber **102** by the induced vacuum through a leak path defined between the dispensing section **46** and the inlet opening **104** of the sealing flange **166**. The patient P may support the base **150** with her hand to prevent sagging of the base **150** that would otherwise tend to cause the sleeve member **180** to collapse under the weight of the base **150**. The patient P may also support the head **110** with a hand. In some embodiments, the patient's inhalation suction draws the base **150** and the head **110** together. According to some embodiments, the base **150** and the head **110** are not forced together other than by the inhalation force, so that in order to collapse the breathing chamber, the patient must exert sufficient negative pressure within the chamber **102** to move the base **150** to the head **110** solely by negative thoracic pressure without mechanical or manual assistance.

If desired, a face mask **70** (FIG. **12**) can be installed on the mouthpiece **136**. The mask **70** can be fitted onto the patient's face (e.g., to cover both the patient's nose and mouth) and the delivery procedure can otherwise be executed in the same manner as described hereinabove. The blowback relief valve **139** will be located outside of the face mask **70**.

During the inhalation step, the one-way valve **122** permits the mixture M to be drawn out of the inhalation device **100** while preventing air from being blown into the chamber **102** in the event the patient P exhales into the mouthpiece **136**. Pressurization of the chamber **102** from patient exhalation might otherwise cause the medication to be blown out of the device **100**.

The blowback relief valve **139** can facilitate more comfortable and effective use of the inhalation device **100** as well. If it is necessary or desired for the patient to exhale one or more times before fully inhaling the mixture M, the patient can exhale into the mouthpiece **136**. The blowback relief valve **139** permits the exhaled air to exit the mouthpiece **136** without undue backpressure on the patient or breaching the valve **122** (i.e., inflow through the valve **122** into the chamber **102**). The blowback relief valve **139** may allow users, such as children, to inhale and exhale normally without sensing any or an undue restriction or blockage. The valve **139** may be particularly useful in the case of pediatric subjects or elderly patients, in the event the patient coughs, and/or when the inhalation device **100** is used with a mask.

The latch features **130** and **140** (or other suitable features) help to retain the mouthpiece **136** in the deployed position during the preparation and administration steps. The guide wall **132** nests inside the passage **137** of the mouthpiece **136** to reduce or prevent leakage of the mixture M and/or ambient air through the interface between the body **112** and the mouthpiece **136**. The guide wall **132** can also stabilize the mouthpiece **136**.

The mouthpiece **136** may be configured to complement or fit a patient's mouth to facilitate dispersion of the medication throughout the patient's breathing passages. According to some embodiments, a face mask **70** (FIG. **12**) may be detachably mounted on the mouthpiece **136** and used for oronasal or nasal inhalation. The mask may have a flexible sealing member with a slot therein of a size and shape to conformably receive and form a sealed engagement with the mouthpiece **136**. The device **100** may be used with face masks of different sizes to accommodate patients of different sizes.

After the system **10** has been used to administer the dose D to the patient P, the dispenser **15** is withdrawn from the base **150** and the device **100** may be returned to its closed position as described above for storage and/or transport.

In order to facilitate cleaning of the inhalation device **100**, the cover member **160** can be removed from the ring member **152** (by disengaging the groove **162**A from the rib **154**A) to provide convenient and effective access to the interior of the sleeve member **180**, the head **110** and the base **150**. The device **100** can be returned to its operational configuration by replacing the cover member **160** on the ring member **152**.

The present invention can provide a portable therapeutic inhalation device that includes an expandable and collapsible medication receiving breathing bag or spacer chamber for allowing long and slow inhalation of the medication by the patient and that nevertheless is small, compact and lightweight, and may conveniently be carried about, stored and transported when not in use. The inhalation device may be compactly stored so that the device may conveniently and safely be carried about in a pocket or a purse. The device can be reusable and easily cleanable.

In use, the device of the invention provides an expandable and collapsible breathing chamber of relatively large volume for reception of a medication from an aerosol canister and for uniform dispersion of the medication in relatively dilute and nonpressurized form within the chamber. According to some embodiments, in order to inhale the dispersed medication from the chamber, the patient must exert a negative thoracic pressure at the inhalation member in order to collapse the breathing chamber and induce the flow of medication from the chamber into the patient's breathing passages. This in turn encourages and promotes a long and slow inspiration period in order to obtain maximum utilization of the medication and maximum efficacy from the therapeutic exercise.

The inhalation device **100** is adapted for use with dispensers having various form factors and, in particular, dispensers including an MDI unit operably mounted in a holder of the type commonly referred to as a boot. This aspect of the inhalation device may be advantageous in that it enables the user to enjoy features of the holder. In particular, according to some embodiments, the holder includes an integral dose counter **50**. By dispensing the dose from the MDI unit **20** using the holder **40** (through the inhalation device **100**), the user can keep track of the number of doses dispensed from or remaining in the MDI unit **20**.

The valve **122** can prevent the user from blowing the medication out of the chamber **102**. Also, the one-way valve **122** and the trap structure **138** can prevent entry of foreign objects into the device **100** when the device **100** is carried in a pocket or purse, and thereby prevent subsequent inhalation of any such foreign object by the patient.

The medication stored in and delivered from the MDI unit **20** via the device **100** may be any suitable and desired inhalation medication. Exemplary medications include ProAir® HFA (albuterol sulfate), Symbicort® (budesonide/formoterol fumarate dihydrate; includes counter), Advair® HFA (fluticasone propionate and salmeterol; includes counter), and Proventil® HFA (albuterol sulfate).

The method of attaching the sleeve member **180** to the base **150** as described herein with reference to FIGS. **11**A and **11**B can provide a number of advantages. The sleeve member **180** can be more easily, cost-effectively and reliably welded to the outer diameter of the ring member **152**. The weld location is placed outside of the chamber **102** so that it does not present a surface that may be difficult to clean. The number of pieces for assembly of the base **150** and the sleeve member **180** is relatively few. The cover member **160**, when mounted on the ring member **152**, can provide mechanical strain relief between the sleeve member **180** and the ring member **152** by capturing the transitional section **183** of the sleeve member **180**.

The size and volumetric capacity of the chamber **102** may be adjusted to meet the varying needs of various patients by producing the inhalation device of the invention in different

diameters and/or with collapsible sleeve members **180** of various lengths and diameters.

With reference to FIGS. **13-23**, an inhalation device or spacer **200** according to further embodiments of the present invention is shown therein. The inhalation device **200** may be used in conjunction with the MDI unit **20** (FIGS. **1**, **12** and **14**), for example, to form an inhalation system **25** (FIG. **14**) to deliver medication from the dispenser **15** in an air diluted and nonpressurized form to the oronasal breathing passages of a human patient as discussed above with regard to the inhalation device **100**. In the case of the inhalation device **200**, the dispenser **15** can be actuated to inject a prescribed or predetermined metered dose of the medication into a chamber **202** defined by the inhalation device **200**, where the medication dose is mixed with air in the chamber **202** to form a dispersed, gaseous medicine mixture. A patient can then inhale the mixture from the inhalation device **200** through a mouthpiece portion **240** of the inhalation device **200**.

Advantageously, the inhalation device **200** can be collapsed into a relatively compact form factor when not in use, as shown in FIG. **23**.

With reference to FIGS. **13-17**, the inhalation device **200** has a longitudinal axis A-A and includes an outlet end member, assembly, unit or head **210** (hereinafter, the head **210**), an inlet end member **250** (hereinafter, the base **250**), a pliable, flexible bag or sleeve member **280**, and a lid or head cover member **290**. The head **210**, the base **250**, and the sleeve member **280** collectively define the chamber **202**.

The base **250** corresponds to and may be substantially identical to the base **150**. The base **250** includes an inlet opening or aerosol injection port **204** (FIG. **16**) communicating with the chamber **202** to receive the dispenser **15** as discussed above with regard to the base **150**.

The sleeve member **280** corresponds to and may be substantially identical to the sleeve member **180**. The sleeve member **280** can be joined to the base **250** in the same manner as described above for the sleeve member **180** and the base **150**.

The head **210** includes a valve member **220**, a mouthpiece member **230**, and a support ring or back plate **244**. The back plate **244** is affixed to the mouthpiece member **230** with the valve member **220** interposed therebetween to form a unitary assembly. According to some embodiments, the back plate **244** is permanently affixed to the mouthpiece member **230** so that the two cannot be separated and the valve member **220** cannot be removed therefrom without damaging one or more of the components **220**, **230**, **244**. That is, the head **210** and the components **220**, **230**, **244** are not serviceable or replaceable.

With reference to FIGS. **16**, **17** and **19**, the valve member **220** includes a base portion **222**, an integral inhalation valve **224**, and opposed, integral side valve flaps **226**A. Hinge grooves **226**B are defined in the base portion **222** between the base portion **222** and the flaps **226**A. According to some embodiments, the valve member **220** is monolithic.

The inhalation valve **224** is a one-way, self-sealing valve configured to permit air to flow out from the chamber **202** through the mouthpiece portion **240**. The valve **224** includes an entrance opening **224**A, an axially opposing a slit **224**C (defined by opposed edges **224**D), and an axially extending through passage **224**B (FIG. **17**) fluidly connecting the opening **224**B and the slit **224**C. Upon application of a sufficient pressure differential across the slit **224**C, the edges **224**D will separate to form an enlarged opening at the slit **224**C through which an inhalation flow can pass. According to some embodiments and as shown, the inhalation valve **224** is a duckbill valve.

The inhalation valve **224** may be formed of any suitable flexible, resilient material. According to some embodiments, the inhalation valve **224** is unitarily molded and, in some embodiments, is monolithic. According to some embodiments, the inhalation valve **224** is formed of TPE or silicone rubber.

With reference to FIGS. **14-17** and **20**A, the mouthpiece member **230** includes an end wall portion **232**, an annular side wall portion **234**, mounting posts **236**A, locator tabs **236**B, a fluid connector portion **238**, an annular front flange **239**, and the mouthpiece portion **240**. Forwardly directed exhaust ports **218** are defined in an axial end face **232**A (FIG. **18**) of the end wall portion **232**.

The side wall portion **234** includes an annular attachment surface or portion **234**A (corresponding to the attachment portion **116**B of the head **110**) and an annular rib **234**B (corresponding to the rib **116**C of the head **110**). The front end of the sleeve member **280** is affixed to the attachment portion **234**A in the same manner as discussed above with regard to the attachment portion **116**B and the sleeve member **180** (e.g., bonded by heat welding).

The upstanding flange **239** extends forwardly from the end wall portion **232** and defines a front cavity **239**A. Opposing cutouts or slots **239**B (FIG. **14**) are defined in the flange **239**.

The fluid connector portion **238** includes a plurality of partition walls **238**A each having a lower edge **238**B and defining connecting passages **214**A.

The mouthpiece portion **240** defines a through passage **212**A (FIG. **16**) terminating at an inlet opening **212**B and an opposed outlet opening **212**C. A trap structure, filter or grill **242** may be provided in the passage **212**A (e.g., at or proximate the outlet opening **212**C). The trap structure **242** may serve to inhibit or prevent the entry of foreign objects or debris into the mouthpiece **240** as well as to ensure that the valve member **220**, if all or a portion of it were to become detached from between the mouthpiece member **230** and the back plate **244**, is not inhaled by the patient.

The mouthpiece member **230** can be formed of any suitable material. According to some embodiments, the mouthpiece member **230** is unitarily molded. According to some embodiments, the mouthpiece member **230** is monolithic. According to some embodiments, the mouthpiece member **230** is formed of a rigid or semi-rigid polymeric material. According to some embodiments, the mouthpiece member **230** is formed of high density polyethylene (HDPE). According to some embodiments, the mouthpiece member **230** is formed of polymer loaded, blended, mixed or coated with a supplemental material that enhances the anti-static properties of the polymer, such as an olefin grade polyether polypropylene copolymer (e.g., Sanyo Pelestat™).

The back plate **244** (FIGS. **15** and **16**) includes a wafer-shaped body **244**A, post slots **244**B, edge slots **244**C and a through opening **246**. The back plate **244** further includes integral locator ribs **248**A, **248**B defining a valve member locator cavity **248**C complementary to the base portion **222**. The back plate **244** may be formed of the same or different materials than the mouthpiece member **230**. According to some embodiments, the back plate **244** is unitarily molded. According to some embodiments, the back plate **244** is monolithic.

The cover member **290** (FIGS. **15** and **16**) includes an end wall **292** and an annular sidewall **294** depending therefrom. The cover member **290** may further include integral reinforcement ribs **296** on its inner side. The cover member **290** can be formed of any suitable material. According to some embodiments, the cover member **290** is unitarily molded. According to some embodiments, the cover member **290** is

formed of a rigid material such as a thermoplastic, which may be harder than the material of the cover member **160**. In some embodiments, the cover member **290** is formed of high density polyethylene (HDPE). According to some embodiments, the cover member **290** is formed of a material that is less rigid and/or less hard than the mouthpiece member **230**. According to some embodiments, the cover member **290** is formed of an elastomeric material. According to some embodiments, the cover member **290** is formed of a thermoplastic elastomer (TPE) or silicone. According to some embodiments, the cover member **290** is formed of an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™), or equivalent. According to some embodiments, the cover member **290** is formed of silicone rubber. According to some embodiments, the cover member **290** is formed of an elastomer loaded, blended, mixed or coated with a supplemental material that enhances the anti-static properties of the elastomer, such as an olefin grade polyether polypropylene co-polymer (e.g., Sanyo Pelestat™) or equivalent.

The inhalation device **200** can be assembled as follows. The valve member **220** is inserted and mounted on the rear side of the mouthpiece member **230**, as illustrated in FIGS. **20**A and **20**B such that the inhalation valve **224** is received in the mouthpiece passage **212**A and the valve flaps **226**A cover valve ports **214**B at the rear ends of the connecting passages **214**A. The back plate **244** is secured to the rear side of the mouthpiece member **230** such that the valve member base **222** is received in the valve locator cavity **248**C. More particularly, the posts **236**A are received in the slots **244**B and the tabs **236**B are received in the slots **244**C. The posts **236**A may be secured in the slots **244**B by heat staking, adhesive, mechanical interlock, interference fit, or any other suitable means. The assembled head **210** is affixed to the sleeve member **280** as described above.

The valve flaps **226**A and valve seat portions **237** (FIG. **20**A) of the mouthpiece member **230** engaged by the valve flaps **226**A form respective laterally opposed one-way exhalation or blowback relief valves **226**. More particularly, a valve port **214**B is defined at the rearward or inward end of each connecting passage **214**A. Each valve flap **226**A is pressed against its valve seat portion **237** such that it fluidly blocks or seals the valve ports **214**B on its side of the mouthpiece portion **240**.

Furthermore, the back plate **244** and the mouthpiece member **230** define an integral fluid conduit or plenum **216** therebetween (FIGS. **17** and **18**). The conduit **216** fluidly communicates with the exhaust ports **218**.

The inhalation system **25** may be used as follows according to methods of the present invention. Initially, the inhalation device **200** may be placed in the closed position of FIG. **23** so that it is compact for transport, storage or the like. To attain the closed position from the open position, the MDI unit **20** is removed (if necessary) from the device **200**, and the user pushes the head **210** and the base **250** axially together such that the sleeve member **280** is captured therebetween and enveloped by the components **210**, **250**. According to some embodiments, the sleeve member **280** is fully enveloped by the head **210** and the base **250** in the closed position. According to some embodiments, the user may twist or rotate the head **210** and the base **250** relative to one another about the lengthwise axis as the user axially converges the head **210** and the base **250** in order to provide a helical lay or fold of the sleeve member **280** into the cavity defined between the head **210** and the base **250** when the device is in the closed position. The sleeve member **280** may have a configuration or material memory tending to direct the sleeve member **280** to follow the helical path or fold pattern. The head **210** and the base **250** are pushed together until the annular rib **234**B of the head **210** seats in and interlocks with the latch groove **252**B in the interior surface of the ring member **252** to releasably retain the device **200** in the closed position.

For storage and handling, the cover member **290** can be temporarily mounted on the head **210** as shown in FIG. **23**. The lower edge portion of the cover member side wall **294** is captured by interference fit within the flange **239**. According to some embodiments, the cover member **290**, when mounted on the mouthpiece member **230**, provides a substantially air-tight seal therebetween (FIG. **23**). The flange cutouts **239**B can facilitate removal of the cover member **290** by providing access to gripping locations for the user.

When the user desires to administer a dose of the medication from the MDI unit **20**, the user may prepare the dispenser **15** as needed. For example, the user may shake the dispenser **15** and remove the cap **46**C (FIG. **12**) from the dispensing section **46**.

To open the inhalation device **200**, the user may press the tabs **252**C (FIG. **15**) axially away from the head **210** while pushing the end wall **262** (FIG. **16**) of the base **250** toward the head **210** as described above with regard to the inhalation device **100**. In this manner, the head **210** can be released from the base **250** and the head **210** and base **250** can be pulled apart to extend the sleeve member **280**. The cover member **290** is removed before or after opening the device **200**.

The dispensing section **46** of the dispenser **15** is mounted on the base **250** as described above with regard to the device **100**.

The patient places the mouthpiece portion **240** in her mouth and depresses the aerosol canister **22** to discharge and inject the dose of medication into the chamber **202** through the dispensing section **46**. The dose mixes with the air in the chamber **202** and is dispersed into a nonconcentrated or dilute dispersion suspended in the air as an air and medication mixture. The gaseous pressure under which the medication was stored in the canister **22** is dissipated in the chamber **202** and the medication is dispersed in nonpressurized form (i.e., at ambient pressure). The one-way inhalation valve **224** is closed by default and may serve to prevent the premature escape of the dose or the mixture from the chamber **202** and to prevent the patient from exhaling into the chamber **202**.

With the inhalation device **200** charged with the mixture as described above, the patient can slowly inhale the mixture from the device **200** through the mouthpiece portion **240** into the patient's breathing passages and lungs. As the air volume is inhaled from the chamber **202**, ambient air may be drawn into the chamber **202** by the induced vacuum through a leak path defined between the dispensing section **46** and the inlet opening **204**. The patient may support the base **250** with her hand to prevent sagging of the base **250** that would otherwise tend to cause the sleeve member **280** to collapse under the weight of the base **250**. The patient may also support the head **210** with a hand. In some embodiments, the patient's inhalation suction draws the base **250** and the head **210** together. According to some embodiments, the base **250** and the head **210** are not forced together other than by the inhalation force, so that in order to collapse the breathing chamber, the patient must exert sufficient negative pressure within the chamber **202** to move the base **250** to the head **210** solely by negative thoracic pressure without mechanical or manual assistance.

After the system **25** has been used to administer the dose to the patient, the dispenser **15** is withdrawn from the base **250** and the device **200** may be returned to its closed position as described above for storage and/or transport.

During the inhalation step, the one-way inhalation valve **224** permits a flow F1 of the mixture to be drawn out of the

inhalation device **200** as shown in FIG. **21**. The one-way blowback relief valves **226** prevent ambient air from being drawn into the inhalation airstream through the valve ports **214**B.

Meanwhile, if the patient exhales into the mouthpiece portion **240**, the exhalation flow is prevented by the one-way inhalation valve **224** from being blown into the chamber **202** and is instead redirected through the head **210**. More particularly and with reference to FIG. **22**, an exhalation flow of sufficient pressure enters through the mouthpiece outlet opening **212**C (indicated as flow F**2**), flows around the inhalation valve **224** (flow F**3**), flows into and through the connecting passages (flow F**4**), deflects the valve flaps **226**A rearwardly away from their valve seats **237**, flows through the temporarily open valve ports **214**B (flow F**5**), flows through the conduit **216** (flow F**5** continued), and finally flows forwardly (i.e., axially in the direction of the patient) out of the head **210** through the exhaust ports **218** (flow F**6**). The valve flaps **226**A may bend or deflect at the hinge grooves **226**B (which act as living hinges) and/or along the flap bodies.

It will be appreciated that the exhaust valves **226** can provide the advantages and functionality as discussed above with regard to the blowback relief valve **139**.

Because the exhaust ports **218** are located on the front side of the end wall **232** and are surrounded by the front flange **239** in the front cavity **239**A, the risk that the patient will inadvertently block the exhaust ports **218** (e.g., with a finger) is greatly reduced. Also, the cover member **290** when installed will cover the exhaust ports **218** as well as the mouthpiece portion **240** to block intrusion by debris or objects that may interfere with the operation of the inhalation valve **224** or the blowback relief valves **226**.

The mouthpiece portion **240** may be configured to complement or fit a patient's mouth to facilitate dispersion of the medication throughout the patient's breathing passages. If desired, a face mask (e.g., the face mask **70** of FIG. **12**) can be installed on the mouthpiece portion **240**. The mask **70** can be fitted onto the patient's face (e.g., to cover both the patient's nose and mouth) and the delivery procedure can otherwise be executed in the same manner as described hereinabove. It will be appreciated that the mask **70** will not interfere with the operation of the inhalation valve **224** or the exhaust valves **226**.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the invention.

That which is claimed is:

1. A collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser, the MDI dispenser operable to dispense a dose of a medication therefrom, the inhalation device comprising:

an outlet end member including a mouthpiece;

an inlet end member including an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser; and

a tubular, pliable, collapsible sleeve member having first and second opposed ends attached to the inlet end member and the outlet end member, respectively;

wherein the inhalation device is positionable in each of an open position, wherein the outlet end member and the inlet end member are spaced apart and the sleeve member is extended such that the outlet end member, the inlet end member and the sleeve member define a chamber, and a closed position, wherein the sleeve member is collapsed and the outlet end member and the inlet end member are proximate one another and envelope the sleeve member;

wherein, when the inhalation device is in the open position with the MDI dispenser mounted in the MDI dispenser mount structure, a dose of the medication can be dispensed from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece;

wherein the inhalation device includes a latch mechanism to releasably secure the outlet end member to the inlet end member when the inhalation device is in the closed position; and

wherein the inhalation device includes at least one release tab operable by a user to warp the inhalation device to actuate the latch mechanism to release the outlet end member from the inlet end member to open the inhalation device.

2. The inhalation device of claim **1** wherein the MDI dispenser includes an MDI aerosol canister mounted in an MDI holder having a dispensing section, and the inlet port and the MDI dispenser mount structure are configured to receive and engage the dispensing section such that the dispensing section extends through the inlet port.

3. The inhalation device of claim **1** wherein the outlet end member includes a one-way inhalation valve that enables outflow of air from the chamber through the mouthpiece and prevents inflow of air into the chamber through the mouthpiece.

4. The inhalation device of claim **3** wherein the outlet end member includes a one-way blowback relief valve that enables outflow of air from the mouthpiece through the one-way blowback relief valve and prevents inflow of ambient air into the mouthpiece through the one-way blowback relief valve.

5. The inhalation device of claim **3** wherein the mouthpiece includes a grill configured to catch and prevent a component of the one-way inhalation valve from being inhaled through the mouthpiece.

6. The inhalation device of claim **1** wherein the sleeve member is substantially cylindrical when the inhalation device is in the open position.

7. The inhalation device of claim **1** wherein the inlet end member includes a ring member to which the sleeve member is affixed, and a cover member mounted on the ring member, wherein the cover member is removable from and replaceable on the ring member to provide access to the interior of the inhalation device for cleaning.

8. The inhalation device of claim **7** wherein the cover member is formed of a first material including a resilient, deformable elastomer, and the ring member is formed of a second material more rigid than the first material.

9. The inhalation device of claim **1** wherein the sleeve member is formed of a polymeric film having a thickness in the range of from about 4 to 8 mil.

10. The inhalation device of claim 9 wherein the polymeric film has a thickness in the range of from about 4 to 6 mil.

11. The inhalation device of claim 1 wherein the sleeve member is formed of a low density polyethylene (LDPE) film.

12. The inhalation device of claim 11 wherein the LDPE film is an anti-static LDPE film having a surface resistivity of 1×10^{12} Ohms/square or less as measured according to ASTM D257-07.

13. The inhalation device of claim 1 wherein at least a portion of at least one of the outlet end member and the inlet end member is formed of a polymeric material blended and/or coated with a supplemental material that imparts an anti-static property to the polymeric material.

14. The inhalation device of claim 1 wherein one of the outlet end member and the inlet end member includes an annular ring member, the ring member having a radially outwardly facing outer attachment surface and defining a through passage, wherein the sleeve member is bonded to the outer attachment surface and extends through the through passage of the ring member to attach to the other of the outlet end member and the inlet end member.

15. The inhalation device of claim 14 wherein the sleeve member is heat welded to the outer attachment surface.

16. The inhalation device of claim 1 wherein the outlet end member includes a body and the mouthpiece is hingedly coupled to the body to rotate between an extended, deployed position and a retracted, stored position.

17. The inhalation device of claim 1 wherein, when the inhalation device is in the closed position, the outlet end member and the inlet end member fully envelope the sleeve member.

18. The inhalation device of claim 1 wherein:

the latch mechanism includes a first coupling feature on the outlet end member and a second coupling feature on the inlet end member;

in the closed position, the first and second coupling features are engaged with one another to secure the inhalation device in the closed position; and

when the at least one release tab is operated by the user to actuate the latch mechanism to release the outlet end member from the inlet end member to open the inhalation device, the first and second coupling features are thereby disengaged with one another.

19. A method for administering a dose of a medication to a patient from a metered dose inhaler (MDI) dispenser, the method comprising:

a) providing a collapsible inhalation device including:

an outlet end member including a mouthpiece;

an inlet end member including an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser; and

a tubular, pliable, collapsible sleeve member having first and second opposed ends attached to the inlet end member and the outlet end member, respectively;

wherein the inhalation device is positionable in each of an open position, wherein the outlet end member and the inlet end member are spaced apart and the sleeve member is extended such that the outlet end member, the inlet end member and the sleeve member define a chamber, and a closed position, wherein the sleeve member is collapsed and the outlet end member and the inlet end member are proximate one another and envelope the sleeve member;

wherein the inhalation device includes a latch mechanism to releasably secure the outlet end member to the inlet end member when the inhalation device is in the closed position; and

wherein the inhalation device includes at least one release tab operable by a user to warp the inhalation device to actuate the latch mechanism to release the outlet end member from the inlet end member to open the inhalation device;

b) placing the inhalation device in the open position, including using the at least one release tab to warp the inhalation device to actuate the latch mechanism to release the outlet end member from the inlet end member to open the inhalation device;

c) mounting the MDI dispenser in the MDI dispenser mount structure; and thereafter;

d) dispensing a dose of the medication from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece.

20. The method of claim 19 wherein, when the inhalation device is in the closed position, the outlet end member and the inlet end member fully envelope the sleeve member.

21. A collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser, the MDI dispenser operable to dispense a dose of a medication therefrom, the inhalation device comprising:

a rigid, unitary outlet end member including a mouthpiece;

an inlet end member including an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser; and

a tubular, pliable, collapsible sleeve member having first and second opposed ends attached to the inlet end member and the outlet end member, respectively, to define therewith a chamber;

wherein, when the MDI dispenser is mounted in the MDI dispenser mount structure, a dose of the medication can be dispensed from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece;

wherein the outlet end member further includes:

a one-way inhalation valve that enables outflow of air from the chamber through the mouthpiece and prevents inflow of air into the chamber through the mouthpiece; and

a one-way blowback relief valve that enables outflow of air from the mouthpiece through the one-way blowback relief valve and prevents inflow of ambient air into the mouthpiece through the one-way blowback relief valve; and

wherein:

the outlet end member includes a valve member including the one-way inhalation valve;

the one-way inhalation valve is a self-sealing valve;

the outlet end member defines an exhaust port fluidly connected to the mouthpiece;

the outlet end member is configured to direct exhalation air flow from the patient through the mouthpiece, through the one-way blowback relief valve, and out through the exhaust port; and

the exhaust port and the mouthpiece are located on an axial end face of the outlet end member.

22. The inhalation device of claim 21 wherein the sleeve member is formed of a polymeric film having a thickness in the range of from about 4 to 8 mil.

23. The inhalation device of claim 21 wherein:

the outlet end member defines at least one internal conduit fluidly connecting the mouthpiece to the exhaust port; and

the outlet end member is configured to direct exhalation air flow from the patient through the mouthpiece, through the one-way blowback relief valve, through the at least one internal conduit, and out through the exhaust port.

24. The inhalation device of claim 21 wherein:

the outlet end member includes a mouthpiece member and a backplate, and the valve member is captured between the mouthpiece member and the backplate; and

the outlet end member and the backplate define an internal conduit in the outlet end member fluidly connecting the one-way blowback relief valve to the exhaust port.

25. The inhalation device of claim 21 wherein the one-way inhalation valve is a duckbill valve.

26. The inhalation device of claim 21 wherein the valve member further includes an integral, radially extending valve flap forming a part of the one-way blowback relief valve.

27. A method for forming a collapsible inhalation device, the method comprising:

providing an end member including an annular ring member, the ring member having a radially outwardly facing outer attachment surface and defining a through passage;

providing a tubular, pliable, collapsible sleeve member having first and second sleeve sections;

bonding the first sleeve section to the outer attachment surface; and

inverting the sleeve member through itself and routing the second sleeve section through the through passage of the ring member such that the sleeve member is wrapped around the ring member.

28. The method of claim 27 wherein bonding the first sleeve section to the outer attachment surface includes heat welding the first sleeve section to the outer attachment surface.

29. The method of claim 27 wherein the step of inverting the sleeve member through itself and and routing the second sleeve section through the through passage is executed following the step of bonding the first sleeve section to the outer attachment surface.

30. A collapsible inhalation device for use with a metered dose inhaler (MDI) dispenser, the MDI dispenser operable to dispense a dose of a medication therefrom, the inhalation device comprising:

a rigid, unitary outlet end member including a mouthpiece;

an inlet end member including an inlet port and an MDI dispenser mount structure configured to receive and engage the MDI dispenser; and

a tubular, pliable, collapsible sleeve member having first and second opposed ends attached to the inlet end member and the outlet end member, respectively, to define therewith a chamber;

wherein, when the MDI dispenser is mounted in the MDI dispenser mount structure, a dose of the medication can be dispensed from the MDI dispenser into the chamber through the inlet port to mix with air in the chamber and thereby form a mixture of the air and the dose of the medication that can be inhaled by a patient from the chamber through the mouthpiece;

wherein the outlet end member further includes:

a one-way inhalation valve that enables outflow of air from the chamber through the mouthpiece and prevents inflow of air into the chamber through the mouthpiece; and

a one-way blowback relief valve that enables outflow of air from the mouthpiece through the one-way blowback relief valve and prevents inflow of ambient air into the mouthpiece through the one-way blowback relief valve; and

wherein:

the outlet end member includes a valve member including the one-way inhalation valve;

the one-way inhalation valve is a self-sealing valve;

the valve member is unitary;

the valve member further includes an integral, radially extending valve flap forming a part of the one-way blowback relief valve;

the outlet end member defines an exhaust port;

the valve flap is positioned in a closed position wherein the valve flap blocks air from entering the mouthpiece through the exhaust valve; and

opening of the valve flap permits exhalation air from the patient to flow through the mouthpiece and out through the exhaust port.

31. The inhalation device of claim 30 wherein the valve member is monolithic.

32. The inhalation device of claim 30 wherein:

the outlet end member defines at least one internal conduit fluidly connecting the mouthpiece to the exhaust port; and

the outlet end member is configured to direct exhalation air flow from the patient through the mouthpiece, through the one-way blowback relief valve, through the at least one internal conduit, and out through the exhaust port.

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